

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT**

BLUE CROSS AND BLUE SHIELD OF
VERMONT and THE VERMONT HEALTH
PLAN,

Plaintiffs,

V.

TEVA PHARMACEUTICAL INDUSTRIES
LTD., TEVA PHARMACEUTICALS USA, INC.,
TEVA SALES AND MARKETING, INC., and
TEVA NEUROSCIENCE, INC.,

Defendants.

Civil Action No. 5:22-cv-00159

DEFENDANTS' MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

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INTRODUCTION

Defendants Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales and Marketing, Inc. (collectively, “Teva”)¹ developed Copaxone as an innovative therapy for patients suffering from relapsing forms of multiple sclerosis (“MS”). Compl. ¶¶ 43-44, 51. The active ingredient of Copaxone (glatiramer acetate, or “GA”) is exceptionally complex, and the way it works to treat MS is not fully understood.

Unsurprisingly, it took several years for companies seeking to market generic versions of GA to secure approval from the U.S. Food and Drug Administration (“FDA”), since generic applicants faced the daunting task of proving that their products were “the same as” Copaxone. 21 U.S.C. § 355(j)(2)(A). Sandoz, Inc. received approval in April 2015 to market a 20 mg version of generic GA, and Mylan Pharmaceuticals, Inc. received approval in October 2017 to market generic versions of GA in both 20 mg and 40 mg strengths. Compl. ¶ 92; pp. 10-11, *infra*. Since generic entry, competition has been vigorous: Teva offered rebates and discounts at multiple points in the drug distribution chain—to companies that manage prescription-drug benefits, to specialty pharmacies that dispense the drugs, and to patients to lower their out-of-pocket costs. Compl. ¶¶ 111, 189-90. Even so, generic competitors gained significant traction in a short period of time. Teva’s revenue for Copaxone fell by more than two-thirds within two years of Mylan’s generic approval, and its net price plummeted by more than 40% during the same period. *See* Comm. on Oversight & Reform, U.S. House of Representatives, Drug Pricing Investigation: Teva-Copaxone 3, fig. 2, 42, fig. 7 (Sept. 2020) (“House Rept.”).

Plaintiffs are health insurance companies that reimburse plan members for prescription drugs, and they seek to represent a putative class of third-party payors of Copaxone. Compl.

¹ Teva Pharmaceutical Industries, Ltd. (*i.e.*, Teva Israel) has separately moved to dismiss under Rule 12(b)(2) for lack of personal jurisdiction and joins this motion in the alternative only to the extent its Rule 12(b)(2) motion is denied.

¶¶ 24-25, 251. Plaintiffs have filed the epitome of a kitchen sink complaint. The Complaint challenges lawsuits and regulatory petitions filed by Teva more than a decade ago, even though such actions are outside the statute of limitations, protected by the First Amendment, and could not plausibly have delayed FDA approval of generic GA. *E.g., id.* ¶ 89. It also challenges Teva’s alleged efforts to compete with generic products after FDA approval. The Complaint asserts violations of Section 1 and 2 of the Sherman Act, but because indirect purchasers lack statutory standing to pursue claims for damages under federal antitrust law, Plaintiffs raise a myriad of state-law claims. *Id.* ¶¶ 262, 274, 284, 297, 379. None of their claims clears the bar of plausibly alleging unlawful conduct.

Sherman Act: The Complaint advances two basic theories of antitrust harm: Teva engaged in conduct that allegedly (1) delayed generic market entry, and then (2) limited generic uptake. *E.g., Compl.* ¶¶ 84, 102. Neither theory supports a claim. To begin, Plaintiffs’ allegations of generic delay fail because they are all premised on challenging petitioning activity that is immune from antitrust attack under the First Amendment. Plaintiffs fail to plausibly allege that Teva’s lawsuits or agency petitions were “shams.” To the contrary, Teva *won* a significant number of its patent claims, and even where Teva did not prevail, there is no basis to suggest the suits and petitions were objectively baseless or filed in bad faith. The Complaint’s allegations also fail because (1) they do not plausibly allege that Teva’s lawsuits and regulatory petitions delayed generic competition given other unrelated barriers to generic approval, and (2) the lawsuits and petitions were filed outside of the statute of limitations. Thus, the Court should dismiss any claim premised on allegations that Teva was responsible for delaying the approval and launch of generic GA.

The Complaint’s allegations targeting Teva’s alleged conduct following generic entry

also suffer from numerous flaws. As an initial matter, the Complaint fails to plausibly allege a threshold requirement of a monopolization claim—that Teva *maintained* monopoly power after generic entry. To the contrary, even assuming that the relevant product market is limited to GA products (Compl. ¶ 211), the two generic entrants—both major pharmaceutical companies—competed vigorously and quickly gained significant market share. Plaintiffs’ own allegations further undercut any suggestion that Teva had pricing power after generic entry, as they allege that Teva had to compete with generic manufacturers by offering discounts and rebates—conduct that is “entirely inconsistent with the exercise of market power.” *Com. Data Servers, Inc. v. Int’l Bus. Machs. Corp.*, 262 F. Supp. 2d 50, 74 (S.D.N.Y. 2003).

The Complaint also fails to allege that Teva engaged in anticompetitive conduct. Plaintiffs mischaracterize Teva’s efforts to compete (*e.g.*, by entering into rebate contracts, introducing new dosages of Copaxone, and offering patients copay support) as antitrust violations. But stripped of conclusory labels, these allegations merely describe vigorous, legitimate competition by Teva. Plaintiffs’ real grievance is that Teva successfully competed with generic GA products, resulting in some doctors, patients, and other actors in the drug-distribution chain choosing Copaxone. But nothing in the Sherman Act (or state analogues) requires Teva to cede the market to generic competitors without fighting back.

State Claims: The Complaint’s state-law claims also must be dismissed for additional, state-specific reasons. **First**, the Complaint’s state antitrust claims (Counts I-III) must be dismissed because they do not satisfy specific requirements of at least 17 states.

- The claims under Illinois and Puerto Rico are barred in full by the *Illinois Brick* doctrine, and claims under Connecticut, Rhode Island, and Utah law that predate each state’s respective *Illinois Brick* repealer are also barred (Section II.A).
- Plaintiffs fail to allege sufficient interstate conduct and/or effects, as required by California, D.C., Florida, Mississippi, New York, North Carolina, Oregon, Tennessee,

West Virginia, and Wisconsin (Section II.B).

- Plaintiffs cannot bring antitrust claims under Utah law because they are not Utah citizens (Section II.C).
- Plaintiffs cannot pursue antitrust claims under California or Kansas law based on unilateral conduct (Section II.D).

Second, each of the Complaint’s seven consumer-protection claims (Count V) fail to satisfy one or more state-specific requirements.

- The Massachusetts Consumer Protection Act claim is barred by *Illinois Brick* (Section III.A).
- At least two states (New York, Vermont) only allow claims to be brought by “consumers” who (unlike Plaintiffs) made the challenged purchases for their own use (Section III.B).
- Plaintiffs fail to allege deception with requisite particularity, and also fail to allege reliance on deceptive conduct in states that require it (Section III.C).
- In at least six states (California, Delaware, Florida, Massachusetts, New Hampshire, New York), Plaintiffs fail to adequately allege intrastate conduct or an otherwise sufficient connection to the state (Section III.D).

Third, Plaintiffs’ unjust enrichment claim also must be dismissed (Count VI). The Complaint purports to allege unjust enrichment claims under the laws of *every single* U.S. state and territory, but does not plead facts specific to those claims, much less any particular jurisdiction’s law. Even if that basic pleading defect were excused, *Illinois Brick* bars the unjust enrichment claims in the states that apply that doctrine. Moreover, unjust enrichment claims may proceed only when there is no adequate remedy at law, which the Complaint fails to allege.

Finally, many of Plaintiffs’ claims should be dismissed as untimely, as Plaintiffs filed their Complaint more than four years after the conduct they challenge commenced. At a minimum, the statutes of limitations will restrict Plaintiffs’ potential damages period. In several jurisdictions, courts have not recognized the continuing violations doctrine. Nor can fraudulent concealment extend the limitations period, because their conclusory allegations fail to provide a

basis to infer either affirmative concealment by Teva or reasonable diligence by Plaintiffs, particularly since Plaintiffs waited two years to sue after even they admit they were on notice.

For all these reasons, the Court should dismiss the Complaint.

FACTUAL BACKGROUND

I. Statutory Framework For FDA Drug Approval

The Federal Food, Drug and Cosmetic Act governs the approval process to market both new and generic drugs. *See* 21 U.S.C. § 355(b), (j). Before a manufacturer can market a “new drug,” it must submit a “new drug application” demonstrating that the drug is safe and effective for its intended use. *Id.* § 355(b)(1). The applicant also must identify any patents claiming the product or its intended use “for which a claim of patent infringement could reasonably be asserted.” *Id.* § 355(b)(1)(A)(viii).

Applicants for generic drugs use an abbreviated pathway, which lets the manufacturer “piggyback on the safety-and-effectiveness information that the brand-name manufacturer[] submitted.” *In re Rivastigmine Pat. Litig.*, 2005 WL 957426, at *1 (S.D.N.Y. Apr. 25, 2005); *see* Compl. ¶ 79. Such applicants may submit an Abbreviated New Drug Application (“ANDA”) demonstrating that the proposed drug is “the same as” and “bioequivalent to” the brand drug. 21 U.S.C. § 355(j)(2)(A); Compl. ¶ 80. A generic applicant that believes the patents claiming the brand product are either invalid or will not be infringed by the ANDA product must submit what is known as a “paragraph IV” certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). By statute, the submission of an ANDA with a paragraph IV certification constitutes an act of patent infringement, which lets the brand manufacturer file suit. 35 U.S.C. § 271(e)(2). If the brand files suit within 45 days of receiving notice of the paragraph IV certification, the FDA is prohibited from granting final approval of the ANDA for a 30-month period. 21 U.S.C. § 355(j)(5)(B)(iii). But if the court in the patent case rules before 30 months that the patents on

the brand drug are invalid or unenforceable, the stay terminates early. *Id.* § 355(j)(5)(B)(iii)(I). This statutory 30-month stay on FDA approval does not prevent the FDA from reviewing an ANDA, and the agency may grant the application “tentative approval” if it determines that the application is approvable but-for the stay. 21 C.F.R. §§ 314.105(d), 314.107(b)(3).

II. The Prescription Drug Market

A number of entities are involved in getting approved prescription drugs to patients. Compl. ¶¶ 67-68. Typically, manufacturers sell drugs to wholesalers, who then sell the drugs to pharmacies. *Id.* The pharmacy is then reimbursed for the cost of the drug by the patient’s health insurance provider. *Id.* ¶¶ 67-70. Pharmacy Benefit Managers (“PBMs”) often operate in the middle of the distribution chain for prescription drugs, *id.* ¶ 71, “serv[ing] as intermediaries between pharmaceutical manufacturers and pharmacies on the one hand ... and health benefit providers (*e.g.*, insurers, self-insured entities, health maintenance organizations, and public and private health plans) on the other,” *Pharm. Care Mgmt. Ass’n v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005). PBMs manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, and other payors. Compl. ¶¶ 69, 72. In this role, PBMs negotiate with drug manufacturers and pharmacies for rebates and discounts paid to the PBMs’ clients.

PBMs also generate “formularies” for their payor-clients, which are lists of prescription drugs covered by the payors’ healthcare plans. Compl. ¶ 73. If a prescribed drug is not on a PBM’s formulary for a specific payor, the health plan generally will not cover the drug and the patient will be responsible for the full cost. *Id.* ¶ 72. Consequently, drug manufacturers compete to have their drugs included on a PBM’s formularies, including by offering the PBM higher rebates and discounts. *See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 44 F.4th 959, 967 (10th Cir. 2022). The PBM market is highly concentrated, with the three largest PBMs accounting for approximately 80% of the market. Compl. ¶ 71.

This “tremendous market power” gives PBMs considerable leverage in negotiations and allows PBMs “to demand concessions from the manufacturers,” including “volume discounts and rebates.” *Pharm. Care Mgmt. Ass’n*, 429 F.3d at 298.

State law also plays a role in determining which drug manufacturer’s product is dispensed. Most states have enacted drug-selection laws, which either require or allow pharmacists to dispense a generic drug when the prescription identifies the brand drug. Compl. ¶ 160. But states also typically authorize pharmacists to dispense the brand drug, even if a generic substitute is available, where the prescription lists the brand drug and specifies that it should be “dispensed as written.” *Id.* ¶ 195.

III. Approval Of Copaxone And Generic Products

A. The FDA Approves Copaxone 20 mg

Copaxone is used to treat patients with relapsing forms of multiple sclerosis (“MS”). Compl. ¶ 51. Teva received FDA approval to market Copaxone in December 1996, in 20 mg/vial form. *Id.* ¶ 55. In February 2002, the FDA approved Copaxone 20 mg to be administered through daily injections. *Id.* ¶ 166. Unlike typical small-molecule drugs made of simple chemical compounds, Copaxone’s active ingredient—glatiramer acetate—is not a single molecular entity; it is a heterogenous mixture of millions of distinct synthetic polypeptides of varying lengths, sequences, and molecular weights. *See* FDA, Letter Denying Citizen Petition, at 9-10 (Apr. 16, 2015) (“Final Petition Denial”).² Due to these complexities, the drug’s therapeutically active components have yet to be identified. *Id.*

B. Teva Submitted Citizen Petitions Arguing That The ANDA Pathway Was Not Appropriate For Copaxone.

In December 2007, several years after the FDA approved Copaxone 20 mg, another

² www.regulations.gov/document/FDA-2015-P-1050-0012.

pharmaceutical company, Sandoz Inc., submitted the first ANDA to market a generic version of GA 20 mg. Compl. ¶ 92 & n.51. Sandoz is a multi-billion dollar company with significant experience selling generic drugs.³ Teva promptly submitted a “citizen petition” to the FDA arguing that the agency should not approve generic versions of Copaxone. *Id.* ¶ 89 & n.47; *see* Teva, Citizen Petition (Sept. 26, 2008) (“2008 Petition”).⁴ Teva’s petition asserted that the complexities of GA prevented a generic applicant from being able to “conclusively demonstrate that the clinically active polypeptide sequences in its purported generic product are qualitatively and quantitatively the same as” Copaxone, as required to use the ANDA pathway. 2008 Petition, *supra*, at 2, 6, 7, 12 (quotation marks omitted).

By law, the FDA had to respond to citizen petitions within 180 days of submission, 21 U.S.C. § 355(q)(1)(F) (2008), but the agency would deny petitions “without comment” that sought a ruling affecting a “pending application,” such as an ANDA, *see* FDA, *Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act* 12-13 (June 2011).⁵ At all relevant times, the FDA also was prohibited from “delay[ing] approval of a pending [ANDA] because of any request to take any form of action relating to the [ANDA],” and it was authorized to deny a citizen petition that was “submitted with the primary purpose of delaying the approval of an application” and “d[id] not on its face raise valid scientific or regulatory issues.” 21 U.S.C. § 355(q)(1)(A), (E) (2008).

Because applications to market generic GA products were pending, the FDA denied

³ Novartis, Annual Report, at 36 (2017), <https://bit.ly/3Vftz1b> (accessed Dec. 8, 2022).

⁴ <https://www.regulations.gov/document/FDA-2008-P-0529-0001>. A court resolving a motion to dismiss may consider “documents incorporated in the complaint by reference” and “matters of which judicial notice may be taken.” *Success Sys., Inc. v. Excentus Corp.*, 439 F. Supp. 3d 31, 51 (D. Conn. 2020); *see In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 152 (E.D.N.Y. 2018) (taking judicial notice “of the contents of ... three citizen petitions to the FDA” on a motion to dismiss).

⁵ <https://www.regulations.gov/document/FDA-2009-D-0008-0011>.

Teva’s citizen petition without reaching the merits, concluding that it would be “premature and inappropriate” to “render a decision on a specific aspect of an ANDA ... before the [FDA] ... had an opportunity ... to fully consider specific data and information in such an application.” FDA, Letter Denying Citizen Petition, at 3 (Mar. 25, 2009).⁶ In light of the FDA’s approach, Teva had to resubmit several additional citizen petitions from 2009 to 2014, each time reprising its challenge to the approval of ANDAs referencing Copaxone. Compl. ¶¶ 89 & n.47, 91 & n.49.

C. Teva Filed Lawsuits Against Generic Manufacturers Under The Hatch-Waxman Framework To Enforce Its Patents On Copaxone.

Sandoz’s ANDA for 20 mg GA included a paragraph IV certification, prompting Teva to sue for patent infringement. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 876 F. Supp. 2d 295, 307 (S.D.N.Y. 2012). In June 2009, another company—Mylan Pharmaceuticals, Inc.—filed its own ANDA for 20 mg GA, also with a paragraph IV certification. *Id.* at 307-08. Mylan “is one of the world’s leading generic and specialty pharmaceutical companies with over 20,000 employees in its family of companies.” *Eli Lilly & Co. v. Mylan Pharms., Inc.*, 96 F. Supp. 3d 824, 828 (S.D. Ind. 2015). Teva sued Mylan for infringement of seven patents covering Copaxone 20 mg in October 2009. *Teva Pharms. USA, Inc.*, 876 F. Supp. 2d at 308. Teva’s lawsuits against Sandoz and Mylan triggered statutory 30-month stays of FDA approval of the ANDAs, which expired in January 2011 and March 2012, respectively. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I).

Teva prevailed substantially on these claims against Sandoz and Mylan. The district court held that “both Mylan’s and Sandoz’s ANDA[s] infringe[d] all of the asserted claims” of the patents at issue, “and that none of [those] claims [was] invalid or unenforceable.” *Teva Pharms. USA, Inc.*, 876 F. Supp. 2d at 419. The district court then enjoined Mylan and Sandoz from marketing their generic products prior to the expiration of the last of Teva’s patents on

⁶ <https://www.regulations.gov/document/FDA-2008-P-0529-0007>.

September 1, 2015. *See* Final Judgment Order, *Teva Pharms. USA, Inc. v. Sandoz*, No. 1:08-cv-07611 (S.D.N.Y. July 24, 2012), ECF No. 338. The Federal Circuit affirmed in substantial part, but held that a subset of patent claims was indefinite, including for a patent set to expire on September 1, 2015. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1366 n.2, 1375-76 (Fed. Cir. 2013). The district court then modified its injunction to prohibit generic launch before May 24, 2014. *See* Modified Final Judgment, *Teva Pharms. USA, Inc. v. Sandoz*, No. 1:08-cv-07611 (S.D.N.Y. Dec. 20, 2013), ECF No. 355. The Supreme Court later vacated the Federal Circuit’s judgment for applying the wrong standard of review. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 323-24, 336 (2015). On remand, the Federal Circuit held in a 2-1 decision that the remaining claims were indefinite. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1345 (Fed. Cir. 2015).

On April 16, 2015, the FDA approved Sandoz’s ANDA. Compl. ¶ 92. That same day, the agency denied Teva’s final citizen petition. *Id.* In the 43-page decision, the FDA “recognize[d] that approval of ANDAs for glatiramer acetate injection raises complicated scientific and regulatory issues” given the “complexity of Copaxone,” and it announced a multi-factored approach to determining generic “sameness” with GA because “there is no single physicochemical or biological characterization that can demonstrate active ingredient sameness between a generic [GA] injection and Copaxone.” Final Petition Denial, *supra*, at 3-4, 20-21. Ultimately, the FDA disagreed with Teva’s arguments, but it did not suggest that any of Teva’s citizen petitions had been “submitted with the primary purpose of delay[]” or failed to “raise valid scientific or regulatory issues.” 21 U.S.C. § 355(q)(1)(E) (2008).

D. The FDA Approves Copaxone 40 mg And Later Approves ANDAs For 20 mg And 40 mg GA.

In January 2014, the FDA approved Teva’s application to market Copaxone in a 40 mg

dosage to be administered three times a week (rather than daily). Compl. ¶ 167.⁷ The new 40 mg dosage allowed for a “more convenien[t]” regimen for patients, as they would no longer have to undergo daily injections. House Rept., *supra*, at 29. The FDA’s approval triggered a three-year period of marketing exclusivity for Copaxone 40 mg, which lasted until January 28, 2017. *See* 21 U.S.C. § 355(j)(5)(F). Teva immediately began to sell its new product, while it also continued to sell its 20 mg product (which remains available to this day).

The following month, both Sandoz and Mylan filed ANDAs for 40 mg GA, prompting Teva to sue both for patent infringement in September and October 2014. *In re Copaxone Consol. Cases*, 2017 WL 401943, at *8-10 (D. Del. Jan. 30, 2017), *aff’d*, 906 F.3d 1013 (Fed. Cir. 2018). Teva’s three-year statutory exclusivity expired on January 28, 2017. Two days later, after a seven-day bench trial, the court held that the asserted claims were invalid as obvious, *id.* at *25, ending the 30-month statutory stays applicable to those ANDAs. Thus, as of January 2017, no exclusivity or litigation stay blocked the FDA from approving ANDAs for 40 mg GA. Even so, it was not until October 3, 2017—eight months later—that the FDA approved Mylan’s 20 mg and 40 mg ANDAs.⁸ (The FDA approved Sandoz’s 40 mg ANDA in February 2018.⁹)

When these generic competitors entered the market, they took a “substantial” portion of Teva’s sales. Compl. ¶ 219. Indeed, a report issued by a congressional committee—which the Complaint incorporates by reference¹⁰—shows that Teva’s Copaxone revenue fell off a cliff after Mylan’s launch, dropping by almost half in just four months and decreasing by more than two-

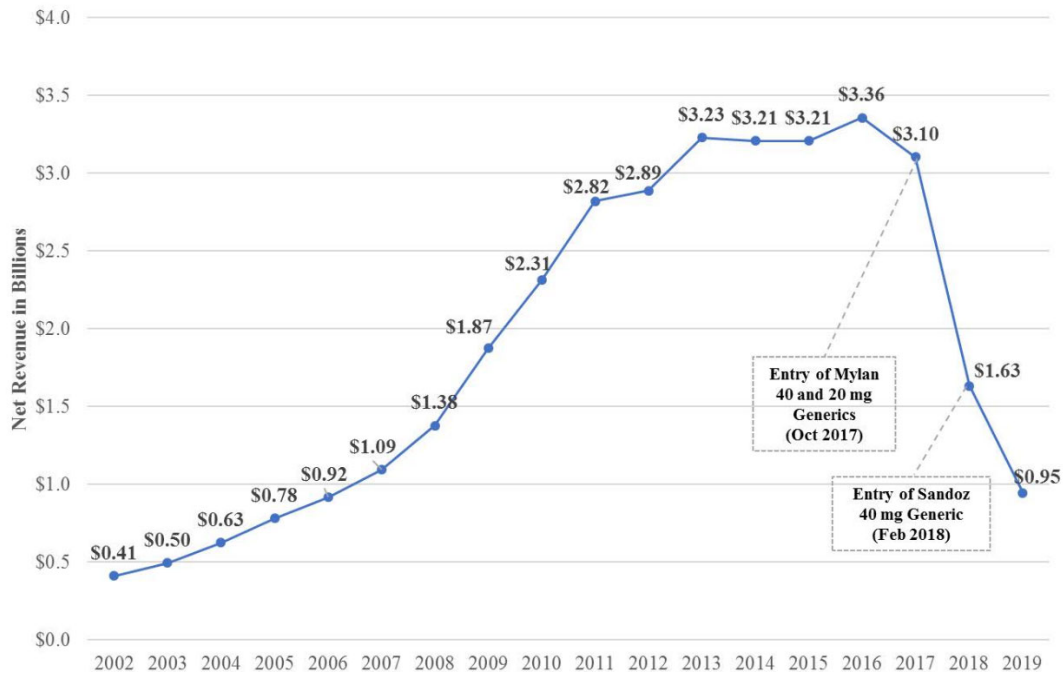
⁷ www.copaxone.com/about-copaxone/dosage-information.

⁸ FDA, ANDA Approval (Oct. 3, 2017), <https://bit.ly/3PsBOER>; FDA, ANDA Approval (Oct. 3, 2017), <https://bit.ly/3uUfyX>.

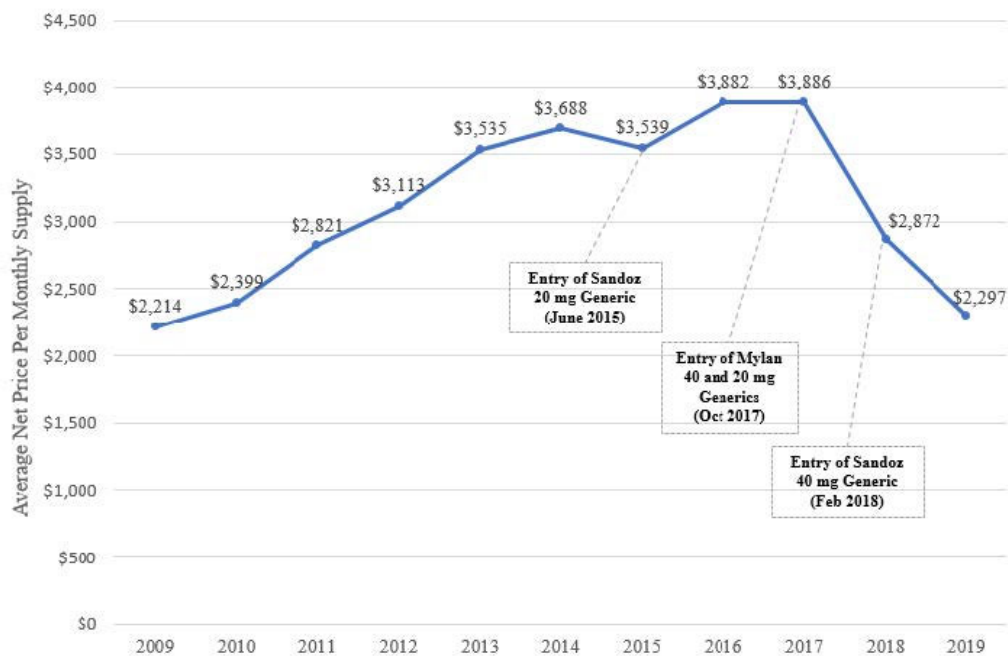
⁹ FDA, ANDA Approval (Feb. 12, 2018), <https://bit.ly/3Vi49PN>.

¹⁰ *See* Compl. ¶¶ 6, 41-42, 57-58, 60-65, 102-03, 116-18, 138, 142-43, 149-54, 169-81, 185-93, 196, 201-02, 208-10.

thirds in less than two years. *See* House Rept., *supra*, at 3, fig. 2.



The net price for Copaxone also dropped by more than 40% in 16 months. *Id.* at 42, fig. 7.



E. The FDA Denied Teva’s Request To Reclassify Copaxone.

In 2019, Teva asked the FDA to reclassify Copaxone as a “biological product,” which would have prevented Sandoz and Mylan from relying on state automatic substitution laws. Compl. ¶¶ 97-101; *see Teva Pharms. USA, Inc. v. FDA*, 514 F. Supp. 3d 66, 83-84 (D.D.C. 2020). The FDA declined Teva’s request, and Teva sued the FDA to challenge its decision. Compl. ¶ 101. The district court ruled in favor of the FDA in a 74-page published opinion. *Id.* ¶ 101 & n.55; *see Teva Pharms. USA, Inc.*, 514 F. Supp. 3d at 117. The court agreed with Teva that the statute did not clearly favor the FDA’s interpretation, but held that the statute was ambiguous and the FDA’s interpretation was reasonable in light of the “complex scientific issues” involved. *Teva Pharms. USA, Inc.*, 514 F. Supp. 3d at 98-106.

F. Plaintiffs Piggyback On Lawsuits Filed In The District Of New Jersey To Challenge Teva’s Efforts To Compete With Generic Manufacturers.

In June 2021, Mylan sued Teva in the District of New Jersey for alleged violations of Section 2 of the Sherman Act, the Lanham Act, and New Jersey law. Mylan’s antitrust claim alleged that Teva filed lawsuits and petitions to the FDA to delay generic entry, and then sought to limit generic uptake after FDA approval. Complaint ¶¶ 101-11, 233-48, *Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd.*, No. 2:21-cv-13087 (D.N.J. June 29, 2021), ECF No. 1. Nearly eight months after Mylan filed its complaint, four sets of plaintiffs filed class-action complaints against Teva in the District of New Jersey—one set of plaintiffs seeking to represent a putative class of direct purchasers of Copaxone (“DPP Plaintiffs”), and three sets of plaintiffs seeking to represent classes of third-party payors who reimbursed patients for Copaxone (“TPP Plaintiffs”). *See* Compl., Consol. Compl., *In re Copaxone Antitrust Litig.*, No. 2:22-cv-01232 (D.N.J. Mar. 8, 2022; Apr. 29, 2022), ECF Nos. 2, 31.

On August 22, 2022, Plaintiffs brought this lawsuit seeking to represent a class of third-

party payors. Compl. ¶ 251. The Complaint’s allegations mirror those in the New Jersey complaints. *See* No. 5:22-cv-00159 (D. Vt. Sept. 26, 2022), ECF No. 23 at 2-6; ECF No. 23-1. Like Mylan, Plaintiffs allege that Teva sought to delay FDA approval of generic products by filing patent lawsuits and petitions to the FDA (Compl. ¶¶ 84-101) and by introducing and promoting a new 40 mg dosage of Copaxone (*id.* ¶¶ 157-85). Also like both Mylan’s and the New Jersey class-action complaints, Plaintiffs challenge Teva’s efforts to compete after generic entry, including Teva’s alleged rebates to PBMs and specialty pharmacies to receive a favorable formulary position (*id.* ¶¶ 187-93), Teva’s alleged donations to foundations to provide copay support to Medicare patients (*id.* ¶¶ 118-56), and Teva’s alleged efforts to persuade doctors to prescribe Copaxone DAW (*id.* ¶¶ 194-210). Finally, like the New Jersey class-action complaints, Plaintiffs allege that Teva’s copay support program for patients on private insurance is unlawful. *Id.* ¶¶ 107-17. Plaintiffs seek declaratory and injunctive relief under the federal Sherman Act, bring damage claims under the antitrust and/or consumer-protection laws of 30 jurisdictions, and seek restitution or disgorgement for unjust enrichment under the laws of “all U.S. states and territories.” *Id.* ¶¶ 262-386.

LEGAL STANDARD

To survive a motion to dismiss, a complaint must allege “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.” *Smith v. Loc. 819 I.B.T. Pension Plan*, 291 F.3d 236, 240 (2d Cir. 2002). Given “the unusually high cost of discovery in antitrust cases” that can “push cost-conscious defendants to settle even anemic cases,” courts should apply pleading requirements rigorously to avoid the time and “potentially enormous expense” associated with litigating “largely groundless claim[s].” *Twombly*, 550 U.S. at 558-59 (citations omitted).

ARGUMENT

I. The Complaint Fails To Plausibly Allege A Sherman Act Claim.

To state a claim for monopolization under Section 2, a plaintiff must allege: “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 105 (2d Cir. 2002). “A monopolist willfully acquires or maintains monopoly power when it competes on some basis other than the merits.” *Dial Corp. v. News Corp.*, 165 F. Supp. 3d 25, 34 (S.D.N.Y. 2016) (citation omitted). Similarly, to allege a claim of attempted monopolization, a plaintiff must allege “(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.” *PepsiCo, Inc.*, 315 F.3d at 105. And to plead a claim under Section 1 of the Sherman Act, a plaintiff must plausibly allege “(1) a combination or some form of concerted action between at least two legally distinct economic entities that (2) unreasonably restrains trade.” *Geneva Pharms. Tech. Corp. v. Barr Lab’ys Inc.*, 386 F.3d 485, 506 (2d Cir. 2004); *see also Doron Precision Sys., Inc. v. FAAC, Inc.*, 423 F. Supp. 2d 173, 182 n.10 (S.D.N.Y. 2006) (“[B]oth Sections 1 and 2 require a similar showing of anticompetitive conduct”). Moreover, an antitrust plaintiff must also plausibly allege that its injury was “caused by the defendant’s violation of the antitrust laws.” *Irvin Indus., Inc. v. Goodyear Aerospace Corp.*, 974 F.2d 241, 244 (2d Cir. 1992).

“It is axiomatic that the antitrust laws were passed for the protection of competition, not competitors.” *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (quotation marks and emphasis omitted). Thus, to plausibly allege a Sherman Act claim, it is not enough to plead that “the defendant has engaged in unfair or predatory tactics.”

Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 459 (1993) (quotation marks omitted). “Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws[.]” *Brooke Grp. Ltd.*, 509 U.S. at 225. Rather, an antitrust plaintiff must identify “conduct which unfairly tends to destroy competition itself.” *Spectrum Sports, Inc.*, 506 U.S. at 458. These principles hold true in cases involving alleged monopolists. It “is in the interest of competition to permit dominant firms to engage in vigorous competition, including price competition,” *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 116 (1986), as this is necessary “[t]o safeguard the incentive to innovate,” *Verizon Commc’ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

A. Plaintiffs’ Allegations That Teva Delayed Competition By Filing Petitions And Lawsuits Cannot Support A Claim For Antitrust Liability.

Plaintiffs allege that Teva “engaged in a decades-long campaign of filing objectively baseless patent litigation and citizen petitions as an anticompetitive weapon” to “block competition from generic versions” of Copaxone. Compl. ¶ 84. Plaintiffs’ reliance on these allegations fails for several reasons, and any claim premised on generic delay must be dismissed.

1. Teva’s Petitions And Lawsuits Are Immune Under *Noerr-Pennington*.

Teva’s patent lawsuits and regulatory filings are immune from antitrust liability. “[B]y virtue of the right to petition guaranteed by the First Amendment, attempts to influence ... administrative or judicial action are immune from federal antitrust liability.” *In re Elysium Health-Chromadex Litig.*, 2018 WL 4907590, at *4 (S.D.N.Y. Sept. 27, 2018). Under the *Noerr-Pennington* doctrine, immunity is withheld only if the lawsuit (or other petition) is “a mere sham” to suppress competition. *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993) (“*PRE*”). This is a “narrow exception,” as a plaintiff’s claim must satisfy a two-part test. *Uniroyal Chem. Co. v. Syngenta Crop Prot., Inc.*, 2006 WL 516749, at *6 (D.

Conn. Mar. 1, 2006). First, the lawsuit or petition “must be objectively baseless in the sense that no reasonable [party] could realistically expect success on the merits.” *PRE*, 508 U.S. at 60. Second, the suit or petition must be intended to “use ... the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon.” *Id.* at 60-61.

Courts may decide the applicability of the *Noerr-Pennington* doctrine on a motion to dismiss when immunity does not depend on disputed facts.¹¹ Because Plaintiffs allege no facts plausibly supporting an exception to *Noerr-Pennington* immunity, their claims attacking Teva’s petitioning activity must be dismissed.

a. The Complaint Does Not Plausibly Allege That Teva’s Lawsuits Or Petitions Were “Objectively Baseless.”

The Complaint cannot overcome *Noerr-Pennington* immunity for Teva’s patent lawsuits or citizen petitions because it does not plausibly allege that they were objectively baseless.

Plaintiffs face an uphill battle when alleging that a patent infringement suit under the Hatch-Waxman Act (like those at issue here) was a sham because “the act of submitting an ANDA [is] itself an act of infringement.” *AstraZeneca AB*, 2010 WL 2079722, at *4. Therefore, an infringement suit “filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification.” *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 149 (3d Cir. 2017); *see also Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014) (“[I]t will be a rare case in which a patentee’s assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a

¹¹ *See, e.g., Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 58-62 (2d Cir. 2016) (dismissing antitrust claim based on *Noerr-Pennington* on a motion to dismiss); *AstraZeneca AB v. Mylan Lab’ys, Inc.*, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) (same), *aff’d*, 412 F. App’x 297 (Fed. Cir. 2011); *Bath Petroleum Storage, Inc. v. Market Hub Partners, LP*, 229 F.3d 1135 (2d Cir. 2000) (same); *Marchon Eyewear, Inc. v. Tura, LP*, 2002 WL 31253199, at *7-9 (E.D.N.Y. Sept. 30, 2002) (same).

claim that the patentee has engaged in sham litigation.”). The Complaint does not plausibly allege that any of Teva’s patent suits meet this demanding standard. Beginning with its suits on the 20 mg product, Teva *won* across-the-board in the district court and preserved much of that victory on appeal. *See* pp. 9-10, *supra*. Understandably, Plaintiffs do not even try to allege that these suits were objectively baseless.¹² Plaintiffs do allege in conclusory fashion that Teva’s lawsuits to enforce its patents on the 40 mg product “were objectively baseless,” Compl. ¶¶ 94-95 & n.52, but that allegation is unsupported and contrary to the public record. Teva’s infringement suit was vigorously litigated, resulting in a seven-day bench trial, a detailed district court opinion, and a published opinion from the Federal Circuit. *See* p. 11, *supra*.

The Complaint likewise provides no basis to infer that any of Teva’s citizen petitions were objectively baseless. The Complaint alleges that Teva’s citizen petitions had “no reasonable expectation of success on the merits,” but relies solely on the allegation that “[e]very one of Teva’s petitions was denied or withdrawn.” Compl. ¶ 91. That allegation falls short. To start, the FDA denied all but the last of Teva’s petitions as “premature,” *without* reaching the merits. *See* pp. 8-9, *supra*. When the FDA did reach the merits, it issued a 43-page decision acknowledging that the approval of generic GA products “raise[d] complicated scientific and regulatory issues,” including challenges in establishing “active ingredient sameness” given “the complexity of Copaxone.” Final Petition Denial, *supra*, at 3-4, 20-21; *see* p. 10, *supra* (describing adoption of a new four-part test for establishing bioequivalence). The serious consideration the FDA gave Teva’s arguments undermines any inference that its petitions were a sham. The mere fact that Teva’s arguments “fail[ed] to move the FDA” does *not* suggest they were “false and objectively baseless.” *Apotex*, 823 F.3d at 60-61 (dismissing sham petitioning

¹² Plaintiffs are similarly silent as to the vast majority of Teva’s other patent lawsuits, which they merely list in the Complaint without elaboration. *See* Compl. ¶ 22(C) nn.9-10.

claim); *see also In re Restasis*, 333 F. Supp. 3d at 154 (“a grant or a denial of a citizen petition is rarely dispositive of whether the petition was baseless at the time it was submitted”).

b. The Serial-Petitioning Exception Does Not Apply Here.

Plaintiffs also cannot overcome *Noerr-Pennington* by invoking the exception for “serial” or “automatic” petitioning involving repeat lawsuits or government petitions. To fall within this exception, Plaintiffs must allege a “whole series” of lawsuits or petitions that were “brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.” *Primetime 24 Joint Venture v. Nat’l Broad., Co.*, 219 F.3d 92, 101 (2d Cir. 2000). This theory does not plausibly apply here.

The serial petitioning exception does not apply to Teva’s Hatch-Waxman lawsuits on the 20 mg or 40 mg products. By making the filing of a Paragraph IV notice an act of infringement, the Hatch-Waxman Act deliberately incentivizes brand manufacturers to file patent suits against generic manufacturers seeking to enter the market. *See p. 5, supra*. And the “volume” of a brand manufacturer’s lawsuits is “dependent on the number of generic companies” that file ANDAs for the brand company’s product—a “matter over which [the brand manufacturer] ha[s] no control.” *AstraZeneca AB*, 2010 WL 2079722, at *5. Thus, courts have refused to apply the serial-petitioning exception to Hatch-Waxman lawsuits, because doing so would unfairly “punish” patent holders for engaging in the precise “behavior that Congress sought to encourage.” *Wellbutrin*, 868 F.3d at 158. The Court should not impose such a perverse result.

The other (non-Hatch Waxman) patent lawsuits Plaintiffs cite (Compl. ¶ 22(C) nn.9-10) also do not support a “serial” petitioning exception because the Complaint lacks any allegations to suggest that those lawsuits were “brought pursuant to a policy of starting legal proceedings *without regard to the merits*.” *Primetime 24*, 219 F.3d at 101 (emphasis added). None of those additional suits triggered a stay on the approval of any generic application, and thus their mere

filing did not have any impact on competition—Teva only stood to benefit from those suits *by winning*. Moreover, the lawsuits the Complaint cites cannot support a “serial” exception to *Noerr-Pennington* because they were filed against *different* parties, asserted *different* patents, pertained to *different* products, and were filed over the span of eight years. *See* pp. 9, 11, *supra*; Compl. ¶ 22(C) nn.9-10. Such temporally and topically dispersed proceedings against different defendants do not constitute a “series” in any meaningful sense. *See Primetime 24*, 219 F.3d at 101 (serial-petitioning exception requires “simultaneous and voluminous challenges”); *Marchon Eyewear, Inc. v. Clariti Eyewear, Inc.*, 2005 WL 820497, at *3 (E.D.N.Y. Apr. 6, 2005) (eight lawsuits filed against different defendants was insufficient).

Finally, the serial petitioning exception does not apply to Teva’s citizen petitions because the number of petitions filed is a byproduct of the FDA’s procedures. As discussed, pp. 8-9, *supra*, the FDA’s policy is to refrain from deciding issues raised in a citizen petition that are relevant to a pending ANDA, but the agency also must resolve a citizen petition within a set time period. The FDA thus denied six Teva petitions as “premature,” without reaching their merits (Teva withdrew another) and without delaying generic approval. *See* pp. 8-9, *supra*. As a matter of substance, Teva filed essentially one petition, which the FDA ruled on once.

2. Teva’s Petitions And Lawsuits Did Not Delay FDA Approval Of Generic Products.

Plaintiffs assert that Teva submitted citizen petitions and patent lawsuits under the Hatch-Waxman framework “as an anticompetitive weapon to ... block competition from generic versions of [GA].” Compl. ¶ 84. But the Complaint does not plausibly allege that Teva’s Hatch-Waxman lawsuits or citizen petitions delayed FDA approval of either Sandoz’s or Mylan’s ANDAs. To the contrary, public records show there is no plausible connection between Teva’s petitioning activity and the approval date of either generic product. This pleading omission

mandates dismissal of any claim premised on delayed entry. *See In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 97-99 (2d Cir. 2017) (dismissing Section 2 claim for failure to plausibly allege that anticompetitive conduct delayed generic approval).

a. Plaintiffs Have Not Plausibly Alleged That Teva's Lawsuits Or Petitions Delayed FDA Approval Of Sandoz's 20 mg ANDA.

Teva's Hatch-Waxman lawsuits on the 20 mg ANDAs did not plausibly delay FDA approval. By the time of Sandoz's approval in April 2015, there had been no litigation-based barrier to FDA approval for nearly a year: Teva sued Sandoz in 2008, the statutory 30-month stay expired in January 2011, and the district court's injunction on FDA approval ended in May 2014. *See pp. 9-10, supra*. Once the injunction expired, the FDA was free to approve Sandoz's ANDA, if all other applicable scientific and regulatory requirements were met. But the FDA did not approve Sandoz's 20 mg ANDA until April 2015—11 months later. *See p. 10, supra*.

The Complaint lacks plausible allegations to support its bald conclusion that Teva's citizen petitions "delay[ed] the entry of generics." Compl. ¶ 86. The only potentially relevant allegation is that the FDA rejected Teva's final citizen petition on the same day that it approved Sandoz's generic product. *Id.* ¶ 92. But the Second Circuit has rejected that *exact* theory at the motion-to-dismiss stage, explaining that because the FDA's guidance "favors contemporaneous adjudications," there is no adverse inference that can be drawn "when a citizen petition is denied simultaneously with the grant of an ANDA petition." *Apotex*, 823 F.3d at 60 & n.4. Plaintiffs also ignore controlling law, which prohibits the FDA from delaying generic approval due to a pending citizen petition,¹³ and provides authority to dismiss any petition that is legally baseless and intended to induce delay. 21 U.S.C. § 355(q)(1)(A), (q)(1)(E). The Complaint contains no allegation that the FDA violated this directive. *See Pit River Tribe v. U.S. Forest Serv.*, 615 F.3d

¹³ An exception applies if the FDA determines delay "is necessary to protect the public health," 21 U.S.C. § 355(q)(1)(A), but the agency is not alleged to have made any such finding here.

1069, 1082 (9th Cir. 2010) (“we presume that agencies will follow the law”).

b. Plaintiffs Have Not Plausibly Alleged That Teva’s Lawsuits Or Petitions Delayed FDA Approval Of Mylan’s ANDAs.

The Complaint also fails to plausibly allege that Teva’s lawsuits or petitions delayed approval of Mylan’s 20 mg and 40 mg ANDAs. As noted, Teva’s final citizen petition was submitted and denied in 2015, and so had no conceivable bearing on the timing of FDA approval of Mylan’s ANDAs in October 2017. *See* p. 10, *supra*. Similarly, the lawsuit on the 20 mg product ended long before Mylan’s approval: the relevant 30-month stay ended March 2012, and the district court’s injunction expired in May 2014, but Mylan’s 20 mg ANDA was not approved until October 2017—two years later. As for Teva’s lawsuit on Mylan’s 40 mg ANDA, it could not have delayed FDA approval because Teva’s 40 mg product was entitled to three years of marketing exclusivity, which barred the FDA from approving generic 40 mg until January 28, 2017. *See* p. 11, *supra*; *see Biocad JSC v. F. Hoffmann-La Roche*, 942 F.3d 88, 104 (2d Cir. 2019) (“That a regulatory or legislative bar can break the chain of causation in an antitrust case is beyond fair dispute.”) (Katzmann, C.J., concurring) (quoting *Wellbutrin*, 868 F.3d at 165). The 30-month litigation stay for the 40 mg lawsuit ended on January 30, 2017, but the FDA did not approve Mylan’s 20 mg or 40 mg ANDAs for another eight months.¹⁴

3. Plaintiffs Cannot Rely On Petitioning Activity That Occurred Outside The Statute Of Limitations.

Plaintiffs’ claims premised on allegations that Teva delayed FDA approval of generic applications for Copaxone also must be dismissed as untimely, as the relevant suits and petitions were all filed more than seven years before Plaintiffs brought this suit. *See, e.g.*, 15 U.S.C. § 15b (four-year limitations period for Clayton Act); *see* pp. 63, 65, *infra* (asserted state-law claims

¹⁴ For the same reason, Teva’s lawsuits and petitions could not possibly have delayed the FDA’s later approval of Sandoz’s 40 mg ANDA in February 2018. *See* p. 11, *supra*.

have a limitations period of six years or fewer).

The limitations period for a Sherman Act claim “begins to run when a defendant commits an act that injures a plaintiff’s business.” *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 401 U.S. 321, 338 (1971). In particular, “sham” petitioning claims accrue when the relevant petition (or lawsuit) is filed. *See Perrigo Co. v. AbbVie Inc.*, 2021 WL 4551397, at *8 (D.N.J. Sept. 30, 2021), *aff’d*, 2022 WL 2870152 (3d Cir. July 21, 2022); *P & M Servs., Inc. v. Gubb*, 2008 WL 4185903, at *5 (E.D. Mich. Sept. 8, 2008) (collecting cases), *aff’d*, 372 F. App’x 613 (6th Cir. 2010). This lawsuit was filed on August 22, 2022. Teva’s patent suit on the 20 mg product was filed in October 2009, the patent litigation on the 40 mg product was filed in October 2014, and Teva filed its final citizen petition in March 2015. *See* pp. 9-11, *supra*. Thus, any claim premised on Teva’s lawsuits or petitions is time barred, and Plaintiffs cannot seek damages based on activity that occurred outside the limitations period. *See* pp. 63-70, *infra*.

B. Teva’s Introduction And Promotion Of Copaxone 40 mg Was Not Anticompetitive.

The Complaint alleges that Teva “engaged in a multi-prong campaign” to “switch” doctors and patients to the new 40 mg product “before ... 20mg generics became available”—so-called “product hopping.” Compl. ¶¶ 162, 168. These product-hop allegations fail to plausibly support antitrust liability. “[C]ourts are properly very skeptical about claims that competition has been harmed by a dominant firm’s product design changes.” *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc). After all, “[p]roduct innovation generally benefits consumers” who gain access to new options that may better fit their needs. *N.Y. ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015) (“*Namenda*”). Here, for example, Teva’s 40 mg product provided patients with a less frequent treatment regimen, requiring only three injections per week rather than daily injections. Compl. ¶¶ 166-67. Because

taking Copaxone involves a precise injection protocol, requiring active patient support and training (*id.* ¶ 205), Teva’s three-times-a-week regimen expanded patients’ choice and offered them a “more convenient[t]” treatment option. *See* House Rept., *supra*, at 29.

Plaintiffs try to impugn Teva’s motives and allege that the 40 mg product was not “a significant improvement in convenience.” Compl. ¶ 179. Patients who chose the 40 mg product and cut their injections per week by more than 50% evidently felt differently, but regardless, “simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct.” *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014). Rather, new product introduction can raise antitrust concerns only when “combine[d] ... with some other conduct” that “coerce[s] consumers” and “impede[s] competition.” *Namenda*, 787 F.3d at 654; *see also Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979) (“If a monopolist’s products gain acceptance in the market ..., it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion.”). The Complaint fails to allege any coercion resulting from Teva’s introduction of Copaxone 40 mg.

1. The Complaint Fails To Allege A “Hard Switch.”

Plaintiffs cannot state an antitrust claim based on Teva’s alleged market-shifting strategy because they do not allege that Teva engaged in a “hard switch.” In adjudicating alleged product hops, courts have drawn “an important distinction between hard and soft switches.” *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 269 (D. Mass. 2017). In a “hard switch,” the brand withdraws its old product from the market before generic entry to “force[] patients” to shift to a new patent-protected formulation. *Namenda*, 787 F.3d at 654. By contrast, in a “soft switch,” the brand tries “to persuade patients and their doctors to switch” from the old formulation to a new one “while both [are] on the market.” *Id.* A soft switch does “not have the same

anticompetitive result” as a hard switch, *Asacol*, 233 F. Supp. 3d at 269, and is not actionable, because “the market” remains able to “determine whether one product is superior to another ... so long as the free choice of consumers is preserved,” *Namenda*, 787 F.3d at 654-55.

Here, the Complaint does not allege that Teva executed a “hard switch” when it launched Copaxone 40 mg. Nor could it: Copaxone 20 mg remains on the market and continues to be prescribed to this day. *See* p. 11, *supra*. Because Teva “maintained both products on the market, [it] did not interfere with [generic manufacturers’] freedom to compete ... *as a matter of law*,” but instead “preserved” “consumer choice,” and left generic manufacturers “free[] to compete,” including by encouraging PBMs, patients, and physicians to stay with the 20 mg dosage. *Asacol*, 233 F. Supp. 3d at 269 (emphasis added).¹⁵

Courts have consistently dismissed Sherman Act claims that do not allege a hard switch. *See, e.g., id.*; *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570, at *13 (D. Mass. Sept. 16, 2015) (dismissing claim premised on brand’s alleged efforts “to shift the market away from doses” of Solodyn because the brand “continued selling the [l]egacy [s]trengths” for several years); *Walgreen Co. v. AstraZeneca Pharms., L.P.*, 534 F. Supp. 2d 146, 148, 151-52 (D.D.C. 2008) (dismissing Section 2 claim premised on allegations that AstraZeneca “deliberately switched the market” from Prilosec to Nexium “just as Prilosec’s patent was about to expire” because AstraZeneca kept both products on the market and therefore had not “eliminat[ed] choices available to the consumer”). This Court should reach the same result.

Moreover, because Teva preserved consumer choice by making both dosages of

¹⁵ The Complaint alleges that Teva “‘explored’” whether to “discontinu[e] copay assistance programs for the 20mg dosage,” Compl. ¶ 173, but it does not allege that Teva actually did so, or that it even made any public statement on the issue. To the contrary, the Complaint’s only basis for this allegation is an “[i]nternal” document that was “not for use in promotion.” House Rept., *supra*, at 31. An internal document obviously could not have had any coercive impact.

Copaxone available to patients, the Complaint’s attempts to question the benefits represented by Copaxone 40 mg’s three-times-a-week regimen, Compl. ¶¶ 178-79, are legally irrelevant. “Preference is a matter of individual taste,” making it impossible for courts to “determine with any reasonable assurance whether one product is ‘superior’ to another.” *Berkey Photo*, 603 F.2d at 287; *see also Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, 2015 WL 1736957, at *15 (E.D. Pa. Apr. 16, 2015) (“doubt[ing] that courts could ever fashion” “an intelligible test of innovation ‘sufficiency’”) (citation omitted), *aff’d*, 838 F.3d 421 (3d Cir. 2016). Here, Teva preserved “the free choice of consumers” by leaving the 20 mg product on the market, *Berkey Photo*, 603 F.2d at 287, and inquiries into “Teva’s true motivation” for bringing Copaxone 40 mg to market, Compl. ¶ 182, are not cognizable under the antitrust laws.¹⁶

2. The Complaint Fails To Allege Coercion Absent A “Hard Switch.”

Unable to allege the hard switch, Plaintiffs nonetheless insist that Teva “coerce[d] and induce[d] doctors, pharmacies, and patients” to switch to the 40 mg product. Compl. ¶ 168. These allegations are insufficient as a matter of law.

The Complaint alleges that Teva made the 40 mg product more attractive by pricing the 40 mg product lower than the 20 mg product. Compl. ¶ 169. But there is nothing unusual about a company seeking to win consumers over to a new product with discounts, and Plaintiffs accordingly get nowhere by merely alleging that the introductory price for Copaxone 40 mg was *too low*. “The antitrust laws condemn high prices, not low ones,” making it “wholly

¹⁶ The Complaint relies on a snippet from a “Teva executive” in 2008 questioning whether an “every other day over once daily” dosage “represent[s] a significant improvement in convenience.” Compl. ¶¶ 179, 182. This does not plausibly undermine the obvious consumer benefit from substantially reducing the number of injections, and, in fact, later Teva documents recognize that the company expected the 40 mg product to attract patients “aiming at less injection/more convenience.” House Rept., *supra*, at 29. Plaintiffs’ remaining allegations as to the alleged lack of “scientific rationale/value” of a three-times-a-week regimen have no relevance to whether that regimen offered consumers a more convenient product. Compl. ¶ 179.

inappropriate to use the Sherman Act to oblige [a defendant] to raise its price[s].” *Schor v. Abbott Lab’ys*, 457 F.3d 608, 610-11 (7th Cir. 2006). The Complaint tries to buttress its pricing allegations by asserting that Teva took steps to induce “price separation” by “increas[ing] the price of 20mg Copaxone by 9.8%,” Compl. ¶ 169, but there are no allegations that Teva’s alleged price increase for Copaxone 20 mg was out of step with normal price increases for that product; indeed, the Complaint suggests the opposite. *See id.* ¶ 59.

Next, Plaintiffs allege that Teva “pressured PBMs to make 40mg Copaxone available to participants of health plans” by “threaten[ing] PBMs that it would stop paying the PBMs rebates on 20mg Copaxone unless the PBMs made 40mg Copaxone available on their formularies.” Compl. ¶ 170. According to the Complaint, “one PBM” lost rebates for Copaxone 20 mg, but then added Copaxone 40 mg to its formulary the next year. *Id.* In other words, Plaintiffs allege that Teva offered price incentives (*i.e.*, rebates) to encourage PBMs to include a new product on their formularies. Even if proven true, that allegation does not suggest anticompetitive conduct: “the threat of a lost discount is a far cry from the anticompetitive conduct” courts have found coercive. *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 407 (3d Cir. 2016); *see also In re EpiPen*, 44 F.4th at 998 (similar). Plaintiffs conflate improper coercion with legitimate (and successful) efforts to use price incentives *to increase customer choice* by encouraging PBMs to offer *both* the 20 mg and 40 mg products in their formularies.

Finally, the Complaint alleges that Teva “entered into contracts with one or more PBMs” under which the PBMs agreed to contact physicians and “make them aware of which patients [were] still on Copaxone 20mg” and “encourage them to switch these patients to Copaxone 40mg.” Compl. ¶ 171. The Complaint adds that Teva engaged in its own outreach and “created financial incentives for its sales force” to encourage patients to switch to Copaxone 40 mg. *Id.*

¶ 172. But once again, there is nothing anticompetitive about Teva promoting its product, or with specialty pharmacies doing the same. The antitrust laws do not “prohibit[] market switching through sales persuasion short of false representations or fraud.” *Walgreen Co.*, 534 F. Supp. 2d at 152.¹⁷ And the manner in which Teva structured its internal bonuses (Compl. ¶ 172) has no conceivable relevance to whether Teva’s promotion of Copaxone 40 mg was coercive.

3. The Product-Hop Claim Is Untimely.

Plaintiffs also cannot rely on Teva’s alleged market-shifting efforts to support their federal or state antitrust claims that are subject to limitations periods of four years or fewer. *See* p. 65, *infra*. Plaintiffs allege that Teva’s “switch” to Copaxone 40 mg in 2014 harmed them because the only generic on the market at the time—Sandoz’s 20 mg generic—could not compete with Copaxone 40 mg. Compl. ¶¶ 167-68, 184. But Mylan’s generic 20 mg and 40 mg products were on the market as of October 2017, *see* House Rept., *supra*, at 2—more than four years before this lawsuit was filed. And Plaintiffs have not plausibly alleged that they suffered any continuing injury from the alleged shift after Mylan’s 40 mg product entered the market.

C. Teva’s Efforts To Compete With Generic Versions Of Copaxone Do Not Support Antitrust Liability.

Plaintiffs allege that Teva continued to suppress competition even *after* both Sandoz and Mylan had launched competing generic products (as of October 2017). But Plaintiffs fail to plausibly allege either that Teva maintained monopoly power during this period¹⁸ or that its efforts to compete (*e.g.*, by offering rebates and patient subsidies) were anticompetitive.

¹⁷ The Complaint alleges that Teva made misstatements about Mylan’s generic product. Those allegations do not support a Sherman Act claim. *See* Section I.C.2.c, *infra*. But as relevant here, there are no allegations that Teva made false representations to promote Copaxone 40 mg.

¹⁸ Teva disputes that it exercised monopoly power in a properly defined market during any period, but for purposes of this motion to dismiss, Teva only challenges the allegations that it maintained monopoly power after entry of generic 20 mg and 40 mg GA.

1. Plaintiffs Do Not Plausibly Allege Teva Maintained Monopoly Power.

“In evaluating monopoly power, it is not market share that counts, but the ability to *maintain* market share.” *United States v. Syufy Enters.*, 903 F.2d 659, 665-66 (9th Cir. 1990). “Although there is no fixed percentage market share that conclusively resolves whether monopoly power exists,” *Kolon Indus. Inc. v. E.I. DuPont de Nemours & Co.*, 748 F.3d 160, 174 (4th Cir. 2014), courts have held that a *majority* market share is generally insufficient to establish monopoly power, especially when market share is trending downward, *see Tops Markets, Inc. v. Quality Markets, Inc.*, 142 F.3d 90, 99 (2d Cir. 1998) (finding that typically “a market share below 50% is rarely evidence of monopoly power, a share between 50% and 70% can occasionally show monopoly power”); *In re Inclusive Access Course Materials Antitrust Litig.*, 2021 WL 2419528, at *13 (S.D.N.Y. June 14, 2021) (“Absent additional evidence, however, ‘a 64 percent market share is insufficient to infer monopoly power.’”) (citing *PepsiCo, Inc.*, 315 F.3d at 109). Indeed, “the Supreme Court has never found a party with less than 75% market share to have monopoly power.” *Kolon Indus. Inc.*, 748 F.3d at 174.

The Complaint alleges in conclusory fashion that Teva “maintain[ed] a significant share of the market” after generic entry. Compl. ¶ 221. But Plaintiffs make no attempt to quantify that share or otherwise to provide a basis to infer that Teva retained pricing power in the face of generic competition from Sandoz and Mylan—two multi-billion dollar companies with ample resources to gain market share. *See Tops Markets, Inc.*, 142 F.3d at 98 (identifying “the strength of the competition” as important to assessing claims of monopoly power); *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 580 (S.D.N.Y. 2011) (rejecting as implausible allegations of monopoly power given the “presence of other large competitors in the market”). In fact, the House Report on which Plaintiffs rely undermines the plausibility of continuing market power, as it shows that Teva’s Copaxone revenue dropped by more than two-thirds in

less than two years after Mylan’s launch, while the net price for Copaxone fell by more than 40%. *See* House Rept., *supra*, at 3, fig. 2, 42, fig. 7. This real-world data, incorporated by reference in the Complaint, *see* p. 12, *supra*, shows that generic competition has been effective.

Several of the Complaint’s allegations underscore that generic competition foreclosed the possibility of Teva exercising monopoly power. For example, Plaintiffs allege that Teva responded to generic competition by offering discounts and rebates to PBMs and specialty pharmacies in order to avoid losing Copaxone sales. *See* pp. 30-31, *infra*. These pricing sacrifices are “entirely inconsistent with the exercise of market power.” *Com. Data Servers, Inc.*, 262 F. Supp. 2d at 74; *see also LLM Bar Exam, LLC v. Barbri, Inc.*, 271 F. Supp. 3d 547, 583-84 (S.D.N.Y. 2017), *aff’d*, 922 F.3d 136 (2d Cir. 2019) (dismissing claim for failure to plausibly allege market power, and noting the implausibility of allegations that “an alleged monopolist” had to “discount” its product “to compete”).

2. Teva’s Efforts To Compete With Generic Versions Of Copaxone Do Not Plausibly Support Antitrust Liability.

In addition to failing to plausibly allege that Teva maintained monopoly power after generic entry, the Complaint also fails to plausibly allege that any of the conduct Teva supposedly engaged in to mitigate its erosion of market share qualified as anticompetitive.

a. Teva’s Alleged Rebate Agreements With PBMs And Specialty Pharmacies Were Not Anticompetitive.

The Complaint alleges that Teva “contract[ed] with PBMs and specialty pharmacies to make Copaxone 40mg the drug that was dispensed to health plan member.” Compl. ¶ 187. *First*, the Complaint alleges that Teva contracted with an unnamed number of PBMs, under which the PBMs agreed to “restrict[] generic access at the formulary level” in exchange for rebates. *Id.* ¶¶ 189, 191. *Second*, the Complaint alleges that Teva paid unnamed specialty

pharmacies rebates “so that prescriptions for [GA] would be filled with brand, regardless of whether a generic was prescribed.” *Id.* ¶ 190. These contracts “required the pharmacy to ensure that patients and health plans are left in the same position as if the prescription has been filled with the generic”—in other words, they provided for the sale of Copaxone *at the generic price*. House Rept., *supra*, at 36 n.134.

Stripped of pejorative labels, these allegations merely describe legitimate price competition by Teva at the payor and pharmacy levels. Under the price-cost test, such efforts to compete on price are not subject to antitrust attack. And even if the general rule of reason were applied, the Complaint’s allegations fail to plausibly allege that Teva suppressed competition.

i. The Agreements Are Subject To The Price-Cost Test.

The Complaint’s allegations regarding the alleged PBM and specialty pharmacy contracts boil down to an objection that Teva competed by using rebates to persuade PBMs and specialty pharmacies to agree to the contracts with Teva. Compl. ¶¶ 189-91. Because the use of above-cost price incentives is inherently procompetitive, these allegations cannot sustain a Sherman Act claim. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 269 n.9 (3d Cir. 2012).

“[C]utting prices in order to increase business often is the very essence of competition.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). Courts are thus deeply skeptical of antitrust challenges to discounts and rebates because such challenges risk “chill[ing] the very conduct the antitrust laws are designed to protect.” *Id.* Reflecting this skepticism, courts apply the price-cost test where the plaintiff alleges that a rival’s pricing is the “predominant mechanism of exclusion.” *ZF Meritor, LLC*, 696 F.3d at 275. Under that test, discounts are *per se* procompetitive as long as the prices are above cost. *See Brooke Grp. Ltd.*, 509 U.S. at 222-24. Importantly, “a plaintiff’s characterization of its claim as an exclusive dealing claim does not take the price-cost test off the table.” *ZF Meritor, LLC*, 696 F.3d at 275.

Instead, the price-cost test “extend[s] to above-cost discounting or rebate programs,” so long as “pricing itself operated as the exclusionary tool.” *Id.* at 274-75; *see Valassis Commc’ns, Inc. v. News Corp.*, 2019 WL 802093, at *3, *5-6 (S.D.N.Y. Feb. 21, 2019) (applying price-cost test to “guarantees” paid for exclusive contracts).

Plaintiffs’ claims cannot survive the price-cost test. The Complaint never alleges that Teva’s rebating practices resulted in below-cost pricing; it alleges the opposite. *E.g.*, Compl. ¶ 216. There is also no question that price is the “predominant”—indeed, the only—“mechanism of exclusion” alleged as to the two contracting arrangements. *ZF Meritor, LLC*, 696 F.3d at 275. A firm employing “loyalty discount[s] or rebate[s] to compete with similar products” is exactly the context in which the price-cost test applies. *Eisai, Inc.*, 821 F.3d at 409; *see ZF Meritor, LLC*, 696 F.3d at 275. The Complaint studiously tries to avoid using the term “rebate,” but it (and the House Report) acknowledges that the PBMs and specialty pharmacies entered into the alleged “contracts” with Teva because they were “getting an additional rebate.” Compl. ¶ 191; *see also* House Rept., *supra*, at 36 (stating that Teva “contract[ed] with—and pa[id] rebates to—PBMs and specialty pharmacies”). Indeed, Teva’s contracts with pharmacies required generic-level pricing. House Rept., *supra*, at 36 n.134. The Complaint’s accusation that Teva “block[ed]” generic products (Compl. ¶¶ 189, 193) by competing on price is just word play.

ii. The Complaint Fails To Plead That The Agreements Were Anticompetitive Under The Rule Of Reason.

Even if the Court were to evaluate Teva’s alleged contracts with PBMs and specialty pharmacies under the rule of reason, Plaintiffs still have failed to plead a plausible antitrust claim. “Exclusive dealing arrangements ... possess procompetitive virtues, such as ‘ensuring stable markets and encouraging long-term, mutually advantageous business relationships.’” *Maxon Hyundai Mazda v. Carfax, Inc.*, 2014 WL 4988268, at *9 (S.D.N.Y. Sept. 29, 2014). For

this reason, “[e]xclusive dealing arrangements ... are ‘presumptively legal’ under the Sherman Act.” *Mazda v. Carfax, Inc.*, 2016 WL 7231941, at *4 (S.D.N.Y. Dec. 9, 2016) (quoting *CDC Techs., Inc. v. IDEXX Lab’ys, Inc.*, 186 F.3d 74, 80 (2d Cir. 1999)), *aff’d*, 726 F. App’x 66 (2d Cir. 2018). To successfully challenge an exclusive dealing arrangement, a plaintiff must plead (and then prove) that the exclusivity “foreclose[s] ... a substantial share of the relevant market.” *Mazda*, 2016 WL 7231941, at *4 (emphasis omitted). In evaluating market foreclosure, courts consider (among other factors) the “duration” of the contracts, their “terminability,” the percentage of the market foreclosed, and whether the dominant firm used coercion. *See id.* at *5; *In re EpiPen*, 44 F.4th at 986 (similar); *ZF Meritor, LLC*, 696 F.3d at 271 (similar).

The Complaint does not plausibly allege that the PBM or specialty pharmacy agreements foreclosed a substantial share of the market. Although the Complaint alleges that there are multiple PBMs and specialty pharmacies in the market with varying market shares, Compl. ¶ 71, it does not specify which (or how many) entered contracts with Teva, *id.* ¶¶ 189-90. At most, the Complaint suggests that Teva entered agreements with two PBMs and specialty pharmacies, *id.*, but it does not identify the entities or their market shares, leaving Plaintiffs short of plausibly alleging substantial foreclosure. *See Dickson v. Microsoft Corp.*, 309 F.3d 193, 208-09, 211 (4th Cir. 2002) (complaint did not plausibly allege substantial market foreclosure absent “allegation[s] regarding [the defendants’] power or share in the [relevant] market”); *Eastman v. Quest Diagnostics Inc.*, 724 F. App’x 556, 558-59 (9th Cir. 2018) (similar). The closest Plaintiffs come is to allege that “45% of units [were] targeted via” the alleged contracts, Compl. ¶ 188, but they *do not* allege that Teva actually foreclosed 45% of the market.

The Complaint also lacks any allegations about the duration of Teva’s alleged agreements or whether they were terminable at-will. This is a significant shortcoming: “[E]xclusive dealing

contracts that are ‘short in duration and terminable at will’ generally do not pose a threat of ... anticompetitive effects,” and are often “pro-competitive” because they “allow[] purchasers regularly to select a new supplier, and thus encourage[] both the incumbent and competitor firms to improve prices and product quality.” *Maxon Hyundai Mazda*, 2014 WL 4988268, at *10; *see also Balaklaw v. Lovell*, 14 F.3d 793, 799 (2d Cir. 1994) (recognizing that short-term contracts “actually encourage, rather than discourage, competition, because the incumbent and [its competitors] have a strong incentive continually to improve the [services] and prices they offer to secure the exclusive positions”); *Spinelli v. Nat’l Football League*, 96 F. Supp. 3d 81, 117 (S.D.N.Y. 2015) (holding that exclusive contracts “of no more than three years” that were open for bidding “do not foreclose competition and are not anticompetitive as a matter of law”).

Plaintiffs’ omission is no accident: it is well known that contracts between drug manufacturers and PBMs are renegotiated “regularly, typically on an annual basis,” and are easy for PBMs to terminate. *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 507 F. Supp. 3d 1289, 1354-55 (D. Kan. 2020) (rejecting antitrust claim challenging such agreements because “[p]layers regularly invoked the contracts’ termination provisions” and “frequently renegotiated their rebate percentages,” and collecting similar cases), *aff’d*, 44 F.4th 959 (10th Cir. 2022). Plaintiffs do not allege facts suggesting that Teva’s agreements with PBMs and specialty pharmacies were any more restrictive, which is unsurprising given PBMs’ “tremendous market power.” *See* p. 7, *supra*. This leaves Plaintiffs unable to plausibly allege substantial market foreclosure. *See Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538, 558 (D.N.J. 2019) (dismissing claims challenging exclusive dealing contract between drug company and health plan restricting formulary access where the contracts at issue were for one-year and open to competitive bidding on an annual basis).

Finally, the Complaint does not plausibly allege that Teva engaged in coercive behavior when entering into the challenged agreements. That is not surprising, as “it’s not coercion for a payor to agree to accept a lower price.” *EpiPen Antitrust Litig.*, 507 F. Supp. 3d at 1349-50 (rejecting exclusive dealing claim where the defendant “offered payors a range of rebates conditioned on various formulary placement” and “[i]n some instances ... offered payors greater rebates if they agreed to exclusivity” but the “only consequence for payors who rejected [the] exclusive offers was losing access to greater discounts”). Indeed, the Complaint undermines any inference of coercion by reproducing a document stating that Teva offered a “range” of contracts with PBMs and specialty pharmacies, including *non-exclusive* contracts “allowing access to COPAXONE 40 mg alongside generic[.]” Compl. ¶ 210.

b. Teva’s Alleged Copay Support Program And Charitable Contributions Were Not Anticompetitive.

Plaintiffs next take aim at Teva’s efforts to provide copay support to MS patients. The Complaint alleges that Teva engaged in anticompetitive conduct by providing copay support to patients on private insurance and by donating to charities that pay the copays of Medicare patients prescribed brand or generic GA. Compl. ¶¶ 106-56. Even if credited, these allegations reduce to an objection that Teva secured sales by investing millions of dollars to lower the prices patients pay for Copaxone, which is *procompetitive* conduct.

i. Teva’s Copay Coupons Are Not Anticompetitive.

Plaintiffs allege that Teva “pa[id] the cost-sharing obligations” of patients on private insurance to “‘keep[] patients on’ Copaxone.” Compl. ¶¶ 110-17. But helping patients afford Copaxone is not anticompetitive; to the contrary, “cutting prices to increase business is ‘the very essence of competition.’” *Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 269 (2d Cir. 2001). “As long as low prices remain above predatory levels”—and Plaintiffs do not

allege predatory pricing here—“they neither threaten competition nor give rise to an antitrust injury.” *Id.* Teva is not aware of a single court that has suggested, much less held, that a copay assistance program violates the antitrust laws. Indeed, copay assistance programs are commonly used by brand manufacturers to compete. *See Am. Fed’n of State, Cnty. & Mun. Emps. Dist. Council 37 Health & Sec. Plan v. Bristol-Myers Squibb Co.*, 948 F. Supp. 2d 338, 343 (S.D.N.Y. 2013) (“co-pay subsidy administration has become a ‘cottage industry’”). Plaintiffs’ real objection is that Teva’s copay assistance program was successful, because patients on private insurance stayed with Copaxone, Compl. ¶¶ 114-17, but that is not a basis for deeming patient-level discounts anticompetitive. Price competition may take place at various levels in a complex market, and allegations that Teva channeled cost savings directly to patients—rather than to insurers like Plaintiffs—cannot sustain an antitrust claim.

ii. Teva’s Charitable Contributions Were Not Anticompetitive.

Plaintiffs next try to buttress their antitrust claims with allegations that Teva violated an entirely different law—the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b)—by allegedly making charitable contributions to foundations that pay MS patients’ out-of-pocket costs for Copaxone. Compl. ¶¶ 118-56. In support, Plaintiffs rely on a pending Department of Justice (“DOJ”) lawsuit alleging that Teva violated the AKS by funneling “financial assistance” to Copaxone patients through charities. *Id.* ¶¶ 127-35. Teva disputes the accusation that any of its charitable donations violated the AKS. But even accepting Plaintiffs’ premise, the Complaint’s allegations amount to a claim that Teva’s donations lowered the out-of-pocket expenses of Copaxone patients and thereby “induced” patients to remain on Copaxone. *Id.* ¶¶ 136, 155. Once again, attempts to win business through discounts are “the very essence of competition.” *Virgin Atl. Airways Ltd.*, 257 F.3d at 269.

Plaintiffs’ assertion that Teva’s alleged charitable contributions violated the AKS do not move the antitrust ball. “The Sherman Act is not a panacea for all evils that may infect business life,” *Berkey Photo*, 603 F.2d at 288 n.41, and so “[e]ven unlawful conduct is ‘of no concern to the antitrust laws’ unless it produces an anticompetitive effect,” *Phila. Taxi Ass’n, Inc v. Uber Techs., Inc.*, 886 F.3d 332, 340 (3d Cir. 2018). Plaintiffs therefore cannot support a Sherman Act claim on the theory that engaging in price competition by lowering out-of-pocket costs for patients violated some *other* law. See *Telectronics Proprietary, Ltd. v. Medtronic, Inc.*, 687 F. Supp. 832, 837 (S.D.N.Y. 1988) (dismissing antitrust claim premised on “conspiracy to violate the Medicare laws”); *Wichita Clinic, P.A. v. Columbia/HCA Healthcare Corp.*, 45 F. Supp. 2d 1164, 1192-93 (D. Kan. 1999) (rejecting claim that an AKS violation would “constitute the sort of antitrust injury that would justify a claim under Section 2”).

In fact, the existence of a distinct regulatory regime policing “kickbacks” under the AKS counsels strongly against extending the antitrust laws to punish patient discounts. *Trinko, LLP*, 540 U.S. at 412-13. The AKS provides “a comprehensive bifurcated civil and criminal scheme for addressing fraudulent and abusive payment practices in federal health care programs,” and “complex, detailed regulations” have been promulgated to implement the statute’s requirements. *PPD Enters., LLC v. Stryker Corp.*, 2017 WL 4950064, at *3 (S.D. Tex. Nov. 1, 2017) (citation omitted). There is no reason to stretch antitrust law to an area subject to its own enforcement regime. That is especially true, as doing so would allow an end run around Congress’s decision to give the Attorney General exclusive authority to enforce the AKS. See *Allstate Ins. Co. v. Linea Latina De Accidentes, Inc.*, 781 F. Supp. 2d 837, 850 (D. Minn. 2011). Other courts have similarly found it “suspect” to “permit[] a private plaintiff to bring a monopolization claim when the alleged misconduct derives from the defendant defrauding the government,” *In re EpiPen*, 44

F.4th at 1005 n.28, and have thus rejected attempts by private plaintiffs to repurpose the Sherman Act to challenge alleged AKS violations.¹⁹ This Court should do the same.

c. Teva’s “DAW” Campaign Was Not Anticompetitive.

Plaintiffs also seek to support their antitrust claims with allegations—copied from Mylan’s complaint—that Teva made “false or misleading representations” to persuade doctors to prescribe Copaxone DAW and for patients to request it. Compl. ¶¶ 197, 199, 207. These allegations fall far short of plausibly alleging monopoly conduct.

“[A] plaintiff asserting a monopolization claim based on misleading advertising must overcome a presumption that the effect on competition of such a practice was *de minimis*.” *Nat’l Ass’n of Pharm. Mfrs., Inc. v. Ayerst Lab’ys, Div. of & Am. Home Prods. Corp.*, 850 F.2d 904, 916 (2d Cir. 1988) (quotation marks omitted). This presumption recognizes that there is “a social cost in litigation over” alleged misrepresentations, in part because “the likelihood of a significant impact upon the opportunities of rivals is so small.” *Id.* As a result, “[i]solated business torts, such as falsely disparaging another’s product, do not typically rise to the level of a Section 2 violation.” *Reed Constr. Data Inc. v. McGraw-Hill Cos.*, 49 F. Supp. 3d 385, 420-21 (S.D.N.Y. 2014), *aff’d*, 638 F. App’x 43 (2d Cir. 2016). To overcome the presumption, a plaintiff must plausibly allege that the misrepresentations were “[1] clearly false, [2] clearly material, [3] clearly likely to induce reasonable reliance, [4] made to buyers without knowledge of the subject matter, [5] continued for prolonged periods, and [6] not readily susceptible of

¹⁹ See, e.g., *Digene Corp. v. Third Wave Techs., Inc.*, 536 F. Supp. 2d 996, 1006 (W.D. Wis. 2008) (rejecting effort to premise Section 2 claim on AKS violation), *aff’d*, 323 F. App’x 902 (Fed. Cir. 2009); *Action Ambulance Serv., Inc. v. Atlanticare Health Servs., Inc.*, 815 F. Supp. 33, 34, 37-38 (D. Mass. 1993) (rejecting effort to premise Sherman Act liability on alleged violations of the AKS); *Telectronics Proprietary, Ltd.*, 687 F. Supp. at 837 (similar).

neutralization or other offset by rivals.” *Id.* at 419.²⁰

Plaintiffs’ misrepresentation theory fails for multiple reasons. To start, the Complaint simply recycles allegations from Mylan’s complaint against Teva, without any indication that Plaintiffs or their counsel conducted an independent investigation. Compl. ¶¶ 198-99. Given attorneys’ “nondelegable responsibility” under Rule 11 to independently investigate a complaint’s allegations, *Pavelic & LeFlore v. Marvel Ent. Grp.*, 493 U.S. 120, 126 (1989), courts have rejected efforts to base claims solely on untested allegations from another case, *see, e.g., Attia v. Google LLC*, 2018 WL 2971049, at *15 (N.D. Cal. June 13, 2018); *Geinko v. Padda*, 2002 WL 276236, at *6 (N.D. Ill. Feb. 27, 2002). The Court should do the same.

In any event, Plaintiffs’ borrowed allegations are inadequate, as they do not attribute any specific false or misleading statements to particular Teva representatives, much less describe the circumstances under which any alleged statements were supposedly made. Compl. ¶¶ 194-210. The Complaint also lacks sufficient allegations to establish that the alleged statements were “clearly false.” *Nat’l Ass’n of Pharm. Mfrs., Inc.*, 850 F.2d at 916. For example, although Plaintiffs’ theory depends on an alleged inconsistency between statements made by Teva and the FDA’s approval of Mylan’s product, the Complaint (like Mylan’s complaint) conspicuously does not allege whether Teva’s purported statements came before or after that approval. *E.g.*, Compl. ¶ 196. Similarly, the Complaint alleges that Teva’s sales representatives’ statements “that [patients] would benefit from remaining” on Copaxone were “misleading[]” because Mylan’s generic “contains the same active ingredient” as Copaxone. *Id.* ¶ 207. But, as the Complaint acknowledges, Teva offers its patients “a variety of services ..., including ... free injection

²⁰ Multiple other circuits have adopted this presumption. *See, e.g., Duty Free Ams., Inc. v. Estee Lauder Cos.*, 797 F.3d 1248, 1268-69 (11th Cir. 2015) (collecting cases); *see also, e.g., Retractable Techs., Inc. v. Becton Dickinson & Co.*, 842 F.3d 883, 895 (5th Cir. 2016) (“false advertising alone hardly ever operates in practice to threaten competition”).

devices, free injection training, and assistance with obtaining insurance coverage,” *id.* ¶¶ 204-05—all of which “benefit” Copaxone patients.²¹

The Complaint also lacks sufficient allegations to infer that the alleged misrepresentations “continued for [a] prolonged period[.]” *Nat’l Ass’n of Pharm. Mfrs., Inc.*, 850 F.2d at 916. Borrowing entirely from Mylan’s complaint, Plaintiffs rely on alleged statements made on unknown dates by a handful of unnamed medical professionals located hundreds of miles apart. Compl. ¶ 199. Such scattered statements are insufficient to allege “the sort of sustained or systematic campaign capable of significantly affecting competition.” *Emulex Corp. v. Broadcom Corp.*, 2010 WL 11595718, at *6 (C.D. Cal. June 7, 2010). At most, the Complaint asserts that the alleged misrepresentations were “long-lasting,” but such threadbare allegations merely reciting the legal standard are insufficient. *Twombly*, 550 U.S. at 555.

The implausibility of Plaintiffs’ theory is compounded by the sophisticated nature of the audience allegedly targeted by the supposed disinformation campaign—*i.e.*, doctors. False advertising may induce reasonable reliance when statements are “made to buyers without knowledge of the subject matter,” *Nat’l Ass’n of Pharm. Mfrs., Inc.*, 850 F.2d at 916, but “sophisticated” audiences are more likely to “attach[] little weight to the statements and [to] instead regard[] them as biased and self-serving,” *Retractable Techs., Inc.*, 842 F.3d at 895. Here, Plaintiffs concede that doctors are “highly knowledgeable decision-makers,” but insist that it is “reasonable for them to trust that [the] drug manufacturers’ statements regarding drugs are supported with evidence” and to “rely” on statements about “the composition of [a] drug.”

²¹ The Complaint also alleges that Teva “misleadingly informed patients that their out-of-pocket expenses (after using Teva’s coupons) might be as low as \$10 per month.” Compl. ¶ 207. This is just a repackaging of Plaintiffs’ objection to Teva’s copay assistance, as the Complaint itself makes clear that Teva *did* lower patients’ out-of-pocket expenses, *id.* ¶¶ 110-17, regardless of whether Plaintiffs view such coupons as consistent with their health plans.

Compl. ¶ 200. That cursory assertion does not provide a plausible basis to infer that doctors who prescribe Copaxone would blindly accept a drug manufacturer's characterization of its *competitor's* product. *See Walgreen Co.*, 534 F. Supp. 2d at 152 (holding that allegations of misrepresentations failed because defendant's "sales necessarily depended on prescriptions written by medical professionals, that is, persons knowledgeable of the subject matter").

Similarly, the Complaint fails to provide a factual basis to infer that the alleged misrepresentations were "not readily susceptible of neutralization." *Nat'l Ass'n of Pharm. Mfrs., Inc.*, 850 F.2d at 916. The Complaint asserts that the alleged misrepresentations "evaded correction or mitigation" because they were communicated "via private portals and targeted conversations." Compl. ¶ 200. But Plaintiffs concede that Mylan's sales representatives "learned" of the alleged misrepresentations, *id.* ¶¶ 198-99, and offer no reason why the alleged misrepresentations were not "readily susceptible of neutralization" at that point, since Mylan could correct the record with its own advertising. *Nat'l Ass'n of Pharm. Mfrs., Inc.*, 850 F.2d at 916. This dooms Plaintiffs' theory because "[t]here can be no harm to competition ... when the victims of false advertising are easily able to counter it." *Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc.*, 323 F.3d 366, 372 (6th Cir. 2003).

Ultimately, Plaintiffs' allegations boil down to a criticism of DAW. *E.g.*, Compl. ¶¶ 196, 207 (describing DAW as "undermining drug substitution laws"). But DAW messaging is how state law enables brands to secure sales despite being disadvantaged by state laws that otherwise require or allow a prescription for a brand company's product to be filled with a generic competitor's product. *See id.* ¶ 160; p. 7, *supra*. Moreover, Plaintiffs' assumption that Teva's DAW success must be the result of misinformation is not plausible given the "obvious alternative explanation" of brand loyalty. *Twombly*, 550 U.S. at 567-68. Taking a dose of

Copaxone is not like swallowing a pill: It involves a precise injection protocol that requires specific injection devices, active patient support, and training. Compl. ¶ 205. Given doctors’ and patients’ decades-long experience with Copaxone, it is unremarkable that many would have been reluctant to alter a tried-and-true regimen with a long-trusted product.

d. Teva’s 2020 Lawsuit Against The FDA Is Immune From Antitrust Attack And Could Not Have Caused Any Antitrust Injury.

Finally, the Complaint alleges that Teva “sought to have the FDA reclassify Copaxone as a ‘biological product’” to “allow[] Copaxone to avoid generic substitution under state drug substitution laws.” Compl. ¶¶ 96-101. These allegations cannot support an antitrust claim.

First, Teva’s request that the FDA reclassify Copaxone as a biological product and subsequent lawsuit are entitled to *Noerr-Pennington* immunity. As discussed, pp. 19-20, *supra*, a lawsuit or agency petition is not a sham if the filing party “intends to achieve” the allegedly anticompetitive goal “by actually succeeding.” *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, 2021 WL 3144897, at *17 (D.N.J. July 26, 2021). But the Complaint only claims that Teva tried to secure an advantage by persuading the FDA or a court to reclassify Copaxone. Compl. ¶¶ 97-101. In other words, Mylan accuses Teva not of process abuse, but of merely seeking an *outcome* that Plaintiffs label anticompetitive. *Noerr-Pennington* immunity therefore applies.²²

Second, the Complaint does not plausibly allege that Teva’s actions actually harmed competition, given that the FDA “refused to reclassify Copaxone,” and the district court “dismiss[ed] Teva’s claims.” Compl. ¶ 101. Thus, Teva’s alleged regulatory action and lawsuit cannot support antitrust liability because there is no possible basis to establish causation.

²² Teva’s arguments for reclassifying Copaxone also were not objectively baseless. Teva’s claims were premised on a recent amendment to the statutory definition of “biological product” that neither the FDA nor any court had previously interpreted, Compl. ¶ 97, and which resulted in a 61-page published opinion recognizing that the relevant statute was ambiguous, *Teva Pharms. USA, Inc.*, 514 F. Supp. 3d at 85.

D. Plaintiffs' Defective Theories Of Exclusionary Conduct Do Not Turn Into A Plausible Theory When Combined.

Plaintiffs will likely try to brush past the defects in each of their theories by arguing that Teva's conduct must be evaluated as part of an overall "scheme" to suppress competition. *E.g.*, Compl. ¶ 10. But before Plaintiffs can aggregate the alleged impact of Teva's actions, they must plausibly allege that at least some aspect of Teva's conduct is anticompetitive and exclusionary. "Logically ... if none of the alleged conduct is exclusionary or anticompetitive, it cannot collectively violate section 2 of the Sherman Act." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 2017 WL 3967911, at *8 n.10 (E.D. Pa. Sept. 8, 2017); *see also, e.g., Eatoni Ergonomics, Inc. v. Rsch. in Motion Corp.*, 486 F. App'x 186, 191 (2d Cir. 2012) ("Because these alleged instances of misconduct are not independently anti-competitive, we conclude that they are not cumulatively anti-competitive either.").

Moreover, "not all actions of an alleged violator may be properly considered ... as ingredients in a 'monopoly broth.'" *Valassis*, 2019 WL 802093, at *10. For example, petitioning activity protected by *Noerr-Pennington* cannot be used to establish antitrust liability, "either standing alone or as part of a broader scheme." *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965). Similarly, pricing and contracting activities that are *per se* lawful do not support an "overall scheme" claim, as "the evidence that the practice is anticompetitive is so 'utterly lacking.'" *Valassis*, 2019 WL 802093, at *10 (citation omitted); *see also* Daniel A. Crane, *Does Monopoly Broth Make Bad Soup?*, 76 Antitrust L.J. 663, 669 (2010) ("above-cost price cutting" and "product-design changes" are "immunized from liability" and do not "become illegal based on their cumulative effect"). Thus, allegations regarding Teva's petitioning activity, discounting practices, and its decision to launch a new product without a hard switch cannot give rise to antitrust liability. Nor can Plaintiffs prop up an overall

scheme claim by challenging conduct from outside the limitations period. *See New York v. Facebook, Inc.*, 549 F. Supp. 3d 6, 45-47 (D.D.C. 2021).

In short, whether viewed collectively or individually, Plaintiffs’ allegations that Teva engaged in anticompetitive conduct prohibited by the antitrust laws fall short.

II. Several Of Plaintiffs’ State Antitrust Claims Fail For State-Specific Reasons.

Plaintiffs’ state antitrust claims are premised on the same allegations and suffer from the same deficiencies as their Sherman Act claims. The Court should dismiss those claims as well. *See In re Bystolic Antitrust Litig.*, 583 F. Supp. 3d 455, 497 (S.D.N.Y. 2022) (“Because the Court dismisses the federal antitrust claims ... Plaintiffs’ claims under the antitrust laws of various states—based on the same factual allegations—fail too.”); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 139 (E.D.N.Y. 2003) (similar), *aff’d*, 466 F.3d 187 (2d Cir. 2006); *see also* Appendix A. But even apart from that general failure, Plaintiffs’ claims suffer from numerous state-law specific deficiencies as well.²³ *See also* Appendix B.

A. Plaintiffs’ Claims Under The Laws Of Connecticut, Illinois, Puerto Rico, Rhode Island, And Utah Are Barred In Whole Or In Part By *Illinois Brick*.

Federal antitrust law does not allow indirect purchasers to recover damages. *Ill. Brick Co. v. Illinois*, 431 U.S. 720 (1977). State antitrust laws are “presumed” to follow *Illinois Brick*, unless the state has “expressly passed *Illinois Brick* repealer legislation or interpreted its law in such a way as to override the rule of *Illinois Brick*.” *In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 413 (S.D.N.Y. 2011). Plaintiffs’ claims for damages under Illinois and Puerto Rico antitrust law should be dismissed because these jurisdictions follow *Illinois Brick*, and their

²³ Defendants also preserve for further review the argument that Plaintiffs lack standing to sue under the laws of jurisdictions in which none of the named plaintiffs allegedly suffered any injury. *See, e.g., In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, 2022 WL 736250, at *17 (D. Del. Mar. 11, 2022).

claims under Connecticut, Rhode Island, and Utah law are also barred in part under that doctrine.

Illinois: The Illinois Antitrust Act prohibits “indirect purchasers” from “maintain[ing] a class action in any court of this State ... asserting claims under th[at] Act” with the “sole exception” of the Attorney General acting in *parens patriae* capacity. 740 ILCS 10/7(2). This rule applies in federal court. In *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393 (2010), Justice Stevens’s controlling concurrence explained that in diversity cases federal courts must apply certain state procedural rules that “function as a part of the State’s definition of substantive rights and remedies.” *Id.* at 416-17.²⁴ Following this rule, courts have overwhelmingly held that the Illinois law bars indirect-purchaser class actions in federal court because “[t]he Illinois restrictions on indirect purchaser actions are intertwined with Illinois substantive rights and remedies[.]” *Wellbutrin XL*, 756 F. Supp. 2d at 677.²⁵ “It would be inconsistent to read these provisions together and conclude that the substantive right is intended to be enforceable in courts outside of Illinois, but not the accompanying restrictions.” *Id.* at 676. Plaintiffs’ Illinois antitrust claims should thus be dismissed.

Puerto Rico: Puerto Rico provides a cause of action for “[a]ny person ... injured in his business or property” by unfair competition. P.R. Laws Ann. tit. 10, § 268. That language closely mirrors the Clayton Act, 15 U.S.C. § 15, which does not authorize indirect-purchaser

²⁴ *Albright v. Christensen*, 24 F.4th 1039, 1044 (6th Cir. 2022) (recognizing Justice Stevens’ concurrence as controlling); *James River Ins. Co. v. Rapid Funding LLC*, 658 F.3d 1207, 1217 (10th Cir. 2011) (same); *In re Wellbutrin XL Antitrust Litig.*, 756 F. Supp. 2d 670, 675 (E.D. Pa. 2010) (same and collecting cases).

²⁵ *See, e.g., Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 626 (N.D. Cal. 2020) (granting motion to dismiss end-payor claims under Illinois Antitrust Act); *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 418 (D.N.J. 2018) (adopting majority view that Illinois law bars indirect purchaser class action in federal court); *Wellbutrin XL*, 756 F. Supp. 2d at 677 (similar); *see also In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 723 (N.D. Ill. 2016) (similar); *Solodyn*, 2015 WL 5458570, at *17 (similar); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 408-09 (D. Mass. 2013) (similar).

suits. *See* p. 44, *supra*. Puerto Rico has not passed an *Illinois Brick* repealer statute, and its antitrust law is “generally construed ‘as essentially embodying the jurisprudence relevant to the parallel federal law’”—including the *Illinois Brick* bar. *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 252 (D. Conn. 2015) (citation omitted). “[O]verwhelming authority” has concluded that indirect purchasers like Plaintiffs have no right to bring claims under Puerto Rico’s antitrust statute. *See Opana*, 162 F. Supp. 3d at 723 (collecting decisions).²⁶ Therefore, the Complaint’s Puerto Rico antitrust claims should be dismissed.²⁷

Connecticut, Rhode Island, and Utah: Plaintiffs’ proposed class period stretches back to 2006, Compl. ¶ 251, but Connecticut, Rhode Island, and Utah did not adopt an applicable *Illinois Brick* repealer statute until later. *See* Conn. Gen. Stat. § 35-46a (eff. October 1, 2017; amended October 1, 2018); 6 R.I. Gen. Laws Ann. § 6-36-7 (eff. July 15, 2013); Utah Code Ann. § 76-10-3109(a) (eff. May 1, 2006). None of these statutes applies retroactively. *See Miami Prod. & Chem. Co. v. Olin Corp.*, 2022 WL 3701159, at *5 (W.D.N.Y. Aug. 26, 2022) (Connecticut); *Aggrenox*, 94 F. Supp. 3d at 252 (Rhode Island); *GEICO Corp. v. Autoliv, Inc.*, 345 F. Supp. 3d 799, 842 (E.D. Mich. 2018) (Utah). Accordingly, Plaintiffs cannot recover damages for Connecticut claims prior to October 2017, Rhode Island claims prior to July 15, 2013, or Utah claims prior to May 1, 2006.

²⁶ *See also, e.g., Staley*, 446 F. Supp. 3d at 628; *In re Broiler Chicken Antitrust Litig.*, 2020 WL 4032932, at *2-4 (N.D. Ill. July 15, 2020); *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 373-74 (D.R.I. 2019); *Aggrenox*, 94 F. Supp. 3d at 252; *Solodyn*, 2015 WL 5458570, at *15.

²⁷ The minority view is based on *Pressure Vessels of Puerto Rico, Inc. v. Empire Gas de Puerto Rico*, 137 D.P.R. 497 (P.R. 1994). *See Rivera-Muniz v. Horizon Lines Inc.*, 737 F. Supp. 2d 57, 61 (D.P.R. 2010). But *Pressure Vessels* is unpersuasive because it did not actually address indirect purchaser standing. *See, e.g., Broiler Chicken*, 2020 WL 4032932, at *3-4; *Opana*, 162 F. Supp. 3d at 723; *Aggrenox*, 94 F. Supp. 3d at 252; *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1087 (N.D. Cal. 2014).

B. The Complaint Does Not Allege The Requisite Intrastate Connection.

The Complaint alleges conduct of a national scope that affected *interstate* commerce. Compl. ¶¶ 230-33. But at least eight jurisdictions’ antitrust laws require the challenged conduct or effects to have occurred solely (or primarily) *within* the jurisdiction: D.C., Mississippi, New York, North Carolina, Oregon, Tennessee, West Virginia, and Wisconsin. The Complaint refers merely to alleged “intrastate effects” in conclusory, boilerplate allegations, *id.* ¶ 233, without alleging jurisdiction-specific conduct or effect, *see id.* ¶¶ 262-93. This pleading deficiency requires dismissal of claims under each of these jurisdiction’s antitrust laws.

D.C.: The D.C. Antitrust Act applies only to conduct in restraint of or to monopolize trade or commerce “all or any part of which is within the District of Columbia.” D.C. Code §§ 28-4502, 28-4503. Purchases must “not involve an interstate link[.]” *Sun Dun, Inc. of Wash. v. Coca-Cola Co.*, 740 F. Supp. 381, 397 (D. Md. 1990). Claims must be dismissed where, as here, the Complaint does not allege “any facts specific to [D.C.] and fail[s] to address how [the defendant’s] actions have in any way affected intrastate commerce in [D.C.]” *In re Cast Iron Soil Pipe & Fittings Antitrust Litig.*, 2015 WL 5166014, at *26 (E.D. Tenn. June 24, 2015).

Mississippi: Mississippi’s Antitrust Act, Miss. Code Ann. § 75-21-3, requires that some anticompetitive conduct occur “wholly” within Mississippi. *State ex rel. Fitch v. Yazaki N. Am., Inc.*, 294 So. 3d 1178, 1189 (Miss. 2020); *see also California v. Infineon Techs. AG*, 531 F. Supp. 2d 1124, 1158 (N.D. Cal. 2007) (dismissing claims for failure to allege activity within Mississippi). A “conclusory averment” that the defendant “created a monopoly in both interstate and intrastate commerce” is insufficient. *In re Microsoft Corp. Antitrust Litig.*, 2003 WL 22070561, at *2 (D. Md. Aug. 22, 2003). But that is all the Complaint provides.

New York: New York’s Donnelley Act, G.B.L. § 340, requires a sufficient “impact on intrastate commerce.” *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 2019 WL 1331830,

at *34-35 (S.D.N.Y. Mar. 25, 2019). Where a complaint lacks “any specific allegations ... on intrastate commerce,” and “the activities alleged ... primarily affected interstate commerce,” the plaintiff’s remedy lies under federal law, not the Donnelly Act. *H-Quotient, Inc. v. Knight Trading Grp., Inc.*, 2005 WL 323750, at *5 (S.D.N.Y. Feb. 9, 2005). Here, the Complaint primarily addresses interstate activity and fails to allege how Teva’s actions affected intrastate commerce in New York. Compl. ¶¶ 230-33. The § 340 claim should therefore be dismissed.

North Carolina: North Carolina’s antitrust law, N.C. Gen. Stat. § 75-1 *et seq.*, requires a substantial, rather than merely incidental, in-state injury, which is not satisfied by “allegations that indirect purchasers pa[i]d inflated prices.” *In re Dealer Mgmt. Sys. Antitrust Litig.*, 362 F. Supp. 3d 510, 549 (N.D. Ill. 2019); *see In re Refrigerant Compressors Antitrust Litig.*, 2013 WL 1431756, at *18-19 (E.D. Mich. Apr. 9, 2013) (dismissing claim for failure to “allege ... wrongful conduct in North Carolina”). The Complaint lacks any such allegations.

Oregon: Oregon’s antitrust statute “appl[ies] to intrastate trade or commerce ... involving an actual or threatened injury to a person or property located in [Oregon].” Or. Rev. Stat. § 646.715(2). A claim under this statute must be dismissed where, as here, there are no allegations connecting the alleged conduct to an intrastate transaction or injury. *See Miami Prods. & Chem. Co. v. Olin Corp.*, 546 F. Supp. 3d 223, 244 (W.D.N.Y. 2021); *GEICO Corp.*, 345 F. Supp. at 841 (dismissing Oregon antitrust claim by non-resident plaintiff who alleged only personal injury).

Tennessee: Tennessee’s antitrust law, Tenn. Code Ann. § 47-25-101, requires that “alleged anticompetitive conduct affect[] Tennessee trade or commerce to a substantial degree.” *Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 523 (Tenn. 2005). Plaintiffs’ claim must be dismissed because the Complaint fails to allege “substantial” effects in Tennessee.

See, e.g., Cast Iron, 2015 WL 5166014, at *25; *Jones v. Micron Tech. Inc.*, 400 F. Supp. 3d 897, 925 (N.D. Cal. 2019); *Infineon Techs.*, 531 F. Supp. 2d at 1159; *In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1378 (S.D. Fla. 2001).

West Virginia: West Virginia’s antitrust law, W. Va. Code § 47-18-1, is “directed towards intrastate commerce.” *Anziulewicz v. Bluefield Cmty. Hosp., Inc.*, 531 F. Supp. 49, 53 (S.D.W. Va. 1981). Because the Complaint fails to allege any connection between the alleged wrongful conduct and West Virginia commerce, Plaintiffs’ West Virginia antitrust claim must be dismissed. *See Cast Iron*, 2015 WL 5166014, at *25-26 (dismissing claims because “a plaintiff must show that the wrongful conduct occurred in West Virginia or was felt in West Virginia”).

Wisconsin: Wisconsin’s antitrust statute, Wis. Stat. § 133.03, requires allegations “either that actionable conduct occurred within the state, or that the conduct complained of substantially affects the people of Wisconsin and has impacts in this state.” *Meyers v. Bayer AG*, 735 N.W.2d 448, 455 (Wis. 2007) (quotation marks omitted). Merely alleging “nationwide impacts” is insufficient. *Id.* at 460; *see also In re Urethane Antitrust Litig.*, 663 F. Supp. 2d 1067, 1084 (D. Kan. 2009) (dismissing claims due to “minimal allegations” of impacts in Wisconsin). Plaintiffs do not allege any conduct or substantial impacts within Wisconsin.

C. The Utah Claim Fails For Lack Of Citizenship.

The Utah Antitrust Act provides that only “[a] person who is a citizen of this state or a resident of this state” can bring a claim under the Act. Utah Code Ann. § 76-10-3109(1)(a). “The majority of courts that have been presented with this statute require at least one Utah citizen or resident be a named plaintiff.” *In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 393 (D.N.J. 2018); *see also Lipitor*, 336 F. Supp. 3d at 419 (same). None of the named plaintiffs are citizens or residents of Utah, Compl. ¶¶ 24-25, so their Utah claim must be dismissed.

D. Plaintiffs Cannot Pursue Certain Claims Based On Unilateral Conduct.

California: California's antitrust law, the Cartwright Act, Cal. Bus. & Prof. Code § 16700, does not prohibit unilateral conduct. *Sheet Metal Workers Loc. 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 393-94 (E.D. Pa. 2010). Plaintiffs' Cartwright Act claims are based on monopolization theories premised (at least in part) on unilateral conduct. See Compl. ¶¶ 273.b, 283.b. Thus, these claims should be dismissed to the extent they rely on unilateral conduct.²⁸ See *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 336 F. Supp. 3d 1256, 1313 (D. Kan. 2018).

Kansas: The Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. § 50-101 *et seq.*, does not apply to unilateral conduct, but "prohibits combinations and conspiracies only." *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 283 (D. Mass. 2004); see also *In re Effexor Antitrust Litig.*, 337 F. Supp. 3d 435, 461 (D.N.J. 2018) (recognizing same). Plaintiffs' monopolization claims (Counts I and II) are based on unilateral conduct, including Teva's alleged false statements to doctors and patients. Compl. ¶¶ 267, 273. Thus, the Kansas antitrust claims must be dismissed to the extent premised on alleged unilateral conduct. See *Lipitor*, 336 F. Supp. 3d at 421; *EpiPen*, 336 F. Supp. 3d at 1314.

III. The Complaint Fails To Plausibly Plead Consumer Protection Claims.

The Complaint alleges claims under the seven states' consumer-protection laws: California, Delaware, Florida, Massachusetts, New Hampshire, New York, and Vermont.²⁹ Compl. ¶¶ 297-378. These claims suffer from multiple flaws and should be dismissed.

²⁸ Plaintiffs' Unfair Competition Law claims under Cal. Bus. Prof. Code § 17200 should likewise be dismissed to the extent they are premised on flawed Cartwright Act or federal claims. See *Jones*, 400 F. Supp. 3d at 923.

²⁹ For California and Florida, Plaintiffs bring both antitrust and consumer protection claims based on the same statutes. While Teva addresses these state statutes as a matter of consumer protection for Count V, the same arguments apply to the antitrust theories in Counts I-III.

A. The Massachusetts § 11 Claim Is Barred By *Illinois Brick*.

The Massachusetts Consumer Protection Act (“MCPA”), Mass. Gen. Laws Ch. 93A, provides two mutually exclusive private rights of action, one for consumers (§ 9) and one for businesses (§ 11). *See Cont’l Ins. Co. v. Bahnan*, 216 F.3d 150, 156 (1st Cir. 2000). Plaintiffs bring a § 11 claim only. Compl. ¶¶ 334, 338. Because the *Illinois Brick* rule applies to § 11 claims, Plaintiffs’ § 11 claim must be dismissed. *See, e.g., Loestrin*, 410 F. Supp. 3d at 373.³⁰

B. Plaintiffs Cannot Bring Claims In States That Limit Their Consumer Protection Claims To “Consumers.”

Plaintiffs are two health plans who allege that they “purchased, paid, and/or provided reimbursement for some or all of the purchase price” of Copaxone dispensed to members of their plans. Compl. ¶¶ 24-25. Because they are not “consumers,” they cannot pursue claims under New York’s or Vermont’s consumer-protection laws.

New York: New York’s General Business Law §§ 349 and 350 apply only to transactions that are “consumer-oriented.” *Stutman v. Chem. Bank*, 731 N.E.2d 608, 611 (N.Y. 2000) (§ 349 requires “consumer-oriented” transactions); *Wiseberg v. Toyota Motor Corp.*, 2012 WL 1108542, at *5 (D.N.J. Mar. 30, 2012) (same for § 350). “[C]onsumers” are “those who purchase goods and services for personal, family or household use.” *Sheth v. N.Y. Life Ins. Co.*, 709 N.Y.S.2d 74, 73 (N.Y. App. Div. 2000); *see also In re Caterpillar, Inc., C13 & C15 Engine Prods. Liab. Litig.*, 2015 WL 4591236, at *33 (D.N.J. July 29, 2015) (dismissing claim under § 349 based on failure to satisfy the personal-use requirement).

Plaintiffs’ conclusory allegation that Teva’s conduct was “consumer-oriented” because it

³⁰ *See also In re Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litig.*, 2022 WL 2438934, at *19 (D. Del. July 5, 2022); *In re Aggrenox Antitrust Litig.*, 2016 WL 4204478, at *8 (D. Conn. Aug. 9, 2016); *United Food*, 74 F. Supp. 3d at 1085; *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 762 N.E.2d 303, 308 (Mass. 2002) (holding that *Illinois Brick* applies to indirect purchaser claims under ch. 93A).

“exerted an impact broadly on purchasers of prescription drugs,” Compl. ¶ 325, is insufficient. Plaintiffs are not consumers, “[n]or ... does the fact that consumers were the ultimate end-users convert the transaction into a consumer transaction” for purposes of § 349. *Black Radio Network, Inc. v. NYNEX Corp.*, 44 F. Supp. 2d 565, 583 (S.D.N.Y. 1999); *see also In re Auto. Refinishing Paint Antitrust Litig.*, 515 F. Supp. 2d 544, 552 (E.D. Pa. 2007) (“[W]hen the alleged deceptive act occurs in a transaction between two companies, even when the result of the deception impacts on a consumer, it is not actionable under § 349.”). Indeed, courts have held that third-party payors like Plaintiffs cannot pursue relief under § 349. *See In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 164 (E.D. Pa. 2009). This Court should follow suit.

Vermont: Vermont’s Consumer Protection Act (“VCPA”), 9 V.S.A. § 2451 *et seq.*, only authorizes suits by “consumer[s].” 9 V.S.A. § 2461(b). A consumer is a person who purchases “goods or services ... for the use or benefit of the person’s business or in connection with the operation of the person’s business.” *Id.* § 2451a(1). The VCPA “allows businesses to sue as consumers with respect to the product that they *use* as consumers.” *Aggrenox*, 2016 WL 4204478, at *9. Because the Complaint does not allege that Plaintiffs purchased Copaxone or its generic equivalent for *their* use, the VCPA claims must be dismissed. *See Sergeants Benevolent Ass’n Health & Welfare Fund v. Actavis, plc*, 2018 WL 7197233, at *52 (S.D.N.Y. Dec. 26, 2018) (third-party payor cannot state claim under VCPA “by alleging that it reimbursed for” a drug “on behalf of its insured members”); *Staley*, 446 F. Supp. 3d at 642 (dismissing claims under VCPA by union health insurers); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 355 F. Supp. 3d 145, 161-62 (E.D.N.Y. 2018) (similar); *Aggrenox*, 2016 WL 4204478, at *9 (similar).³¹

³¹ Plaintiffs’ Vermont antitrust claims in Counts I-III should be dismissed for the same reasons as

C. The Complaint Fails To Plausibly Allege Deception.

The Complaint fails to plausibly allege that Teva engaged in deception, as required by several states' consumer-protection laws. State consumer protection claims are subject to the heightened pleading requirement of Federal Rule of Civil Procedure Rule 9(b) when they are premised on allegations of fraud or misrepresentation. *See Olson v. Major League Baseball*, 29 F.4th 59, 71 (2d Cir. 2022); *see also In re Magnesium Oxide Antitrust Litig.*, 2011 WL 5008090, at *1 (D.N.J. Oct. 20, 2011) (dismissing consumer protection claims for failure to satisfy Rule 9(b) to the extent they were based on fraud). Rule 9(b) requires plaintiffs to “(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent.” *Olson*, 29 F.4th at 71.³²

Plaintiffs allege that Teva engaged in fraudulent and deceptive conduct by “[s]ending misleading messaging to patients and doctors,” “[d]efrauding Medicare,” and “[m]isrepresenting” and “[c]oncealing” other aspects of its alleged conduct. Compl. ¶¶ 303, 314, 326, 337, 347, 360, 372. But the Complaint relies on summary characterizations of the allegedly false or deceptive conduct without the factual detail required by Rule 9(b). *See, e.g., id.* ¶¶ 129-48, 198-99. For example, although Plaintiffs assert that Mylan “detailed” examples of false and misleading representations by Teva, they put forward no facts regarding the general timing of

their consumer protection claims. The antitrust remedies provided by 9 V.S.A. § 2465 did not “effectuate a change in Vermont law that would otherwise eliminate [a] Plaintiff’s need to establish its status as a consumer.” *Picket Fence Preview, Inc. v. Zillow, Inc.*, 2022 WL 3597446, at *6 (D. Vt. Aug. 23, 2022) (quotation marks and citation omitted).

³² Plaintiffs antitrust claims are also subject to Rule 9(b)’s heightened pleading standard to the extent they are premised on alleged fraud or misrepresentations. Teva acknowledges that this Court has held that claims under the VCPA are not subject to Rule 9(b), *Whitney v. Nature’s Way Pest Control, Inc.*, 2016 WL 3683525, at *3 (D. Vt. July 6, 2016), but preserves the argument here for future review.

such statements, by or to whom they were made, or the circumstances under which were presented. *Id.* ¶¶ 198-99. Likewise, Plaintiffs do not plausibly allege with factual specificity that anyone relied on Teva’s alleged misrepresentations. At most, the Complaint alleges that it would have been “reasonable” for health care professionals to so rely, *id.* ¶ 200—not that such reliance occurred. These pleading deficiencies require dismissal of several consumer-protection claims.

California: To plead a claim under California’s Unfair Competition Law (“UCL”), Cal. Bus. & Prof. Code § 17200, a plaintiff must allege actual reliance on allegedly deceptive or misleading statements. *In re iPhone 4S Consumer Litig.*, 2013 WL 3829653, at *11 (N.D. Cal. July 23, 2013) (granting motion to dismiss). Rule 9(b) applies to UCL claims. *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). Because the Complaint fails to plead actual reliance and does not satisfy Rule 9(b), this claim must be dismissed.

Delaware: Claims under Delaware’s Consumer Fraud Act (“DCFA”), 6 Del. C. § 2511 *et seq.*, are subject to Rule 9(b). *See Johnson v. Ace Cash Express Inc.*, 2015 WL 4397482, at *3 (D. Del. July 17, 2015) (dismissing DCFA claim for failure to plead with requisite specificity); *Zieger v. Advance Am.*, 2014 WL 7388365, at *5 (D. Del. Dec. 29, 2014) (“an alleged violation of the [DCFA] must be pled with particularity”). Plaintiffs’ DCFA claim is premised on alleged misrepresentations and deceptive acts and thus sounds in fraud. Compl. ¶¶ 372, 376-77. As the Complaint fails to satisfy Rule 9(b), this claim must be dismissed.

Florida: The Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201 *et seq.* (“FDUTPA”) prohibits “unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce[.]” Fla. Stat. § 501.204. The “prevailing view” is that Rule 9(b) applies to FDUTPA claims “where the gravamen of the claim sounds in fraud.” *Hertz Corp. v. Accenture LLP*, 2019 WL 5537997, at *3 (S.D.N.Y. Oct. 25, 2019)

(citation omitted); *Refrigerant Compressors*, 2013 WL 1431756, at *21 (dismissing claim for failure to plead with requisite specificity). Plaintiffs' FDUTPA claim is subject to Rule 9(b), because it is based on allegations that Teva sent "misleading messaging to patients and doctors," defrauded Medicare, misrepresented reasons for introducing 40 mg Copaxone, and misrepresented various other issues. Compl. ¶ 360. Plaintiffs also refer to the challenged conduct as "deceptive acts or practices" and "misrepresentations." *Id.* ¶¶ 364-66. However, Plaintiffs have not alleged sufficient detail regarding where or when such misrepresentations were made or who was involved, so their claims must be dismissed. *See In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 665 (E.D. Mich. 2011) (dismissing FDUTPA claims for failure to specifically allege the details of the false statements and how they were deceptive).

New Hampshire: Claims under the New Hampshire Consumer Protection Act ("NHCPA"), N.H. Rev. Stat. § 358-A:2, are subject to Rule 9(b) to the extent they sound in fraud. *See, e.g., Micronics Filtration Holdings, Inc. v. Miller*, 2018 WL 4845749, at *6 (D.N.H. Oct. 4, 2018); *Gwyn v. Loon Mountain Corp.*, 2002 WL 1012929, at *7-8 (D.N.H. May 15, 2002) (finding NHCPA misrepresentation claim lacked requisite specificity), *aff'd*, 350 F.3d 212 (1st Cir. 2003) Plaintiffs' NHCPA claim sounds in fraud since it is based on misrepresentations, Compl. ¶¶ 314-15, 318-20, but the Complaint fails to provide the requisite particularity. The claim must be dismissed.

New York: New York's General Business Law §§ 349, 350 requires a plaintiff to allege a "deceptive" act or practice that is actually deceptive; "mere anticompetitive conduct alone will not suffice." *In re Lamictal Indirect Purchaser & Antitrust Consumer Litig.*, 172 F. Supp. 3d 724, 752 (D.N.J. 2016); *accord Leider v. Ralfe*, 387 F. Supp. 2d 283, 295-96 (S.D.N.Y. 2005). "A plaintiff is required to plead with specificity the allegedly deceptive acts or practices that

form the basis of a claim.” *Packaged Ice*, 779 F. Supp. 2d at 666 (dismissing § 349 claim for failure to allege deceptive conduct with particularity); *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1051642, at *14 (D. Mass. Apr. 2, 2007) (“[M]ost courts have also held that it is appropriate to require specificity in pleading a violation of Section 349” (quotation marks omitted)). Plaintiffs’ New York claim is based on alleged misleading statements and deceptive conduct, Compl. ¶¶ 326, 330-32, but the Complaint fails to detail the alleged deception with particularity. The claim must be dismissed.

Massachusetts: Claims under the MCPA are subject to Rule 9(b) to the extent the “core allegations effectively charge fraud.” *Mulder v. Kohl’s Dep’t Stores, Inc.*, 865 F.3d 17, 21-22 (1st Cir. 2017) (affirming dismissal of Chapter 93A claim that plaintiff was deceived by advertising for failure to satisfy Rule 9(b)); *see also Valley Container Co., Inc. v. Liberty Mut. Grp., Inc.*, 2020 WL 3270848, at *6 (D. Mass. June 17, 2020) (dismissing Chapter 93A claim based on improper reporting for lack of sufficient particularity). The Complaint alleges that Teva engaged in a range of misleading statements and deceptive conduct, Compl. ¶¶ 337, 340-41, which sounds in fraud, *see Mulder*, 865 F.3d at 21-22. As with its claims under other states’ laws, the Complaint does not allege the requisite particularity.

Vermont: Section 2453 of the VCPA prohibits “[u]nfair methods of competition in commerce, and unfair or deceptive acts or practices.” To establish a claim for deception, Plaintiffs must plausibly allege, among other things, that *they* relied on an alleged misrepresentation. *Lofts Essex, LLC v. Strategis Floor & Décor Inc.*, 224 A.3d 116, 127 (Vt. 2019). The Complaint alleges Teva made misleading statements, Compl. ¶¶ 303, 306-07, but does not allege any misrepresentations were targeted at them or affected their conduct. Their VCPA claims must be dismissed to the extent they rely on deception.

D. Plaintiffs Fail To Adequately Allege An Intrastate Nexus.

Plaintiffs' consumer protection claims under the laws of California, Delaware, Florida, Massachusetts, New Hampshire, and New York also fail, because those states' laws require intrastate conduct or, at least, a significant nexus to the state, which the Complaint fails to plead.

California: The mere sales of products in California is insufficient to sustain a UCL claim by non-California plaintiffs against non-California defendants. "[I]n-state sales alone cannot properly be considered sufficient to establish a nexus with California." *Churchill Vill., L.L.C. v. Gen. Elec. Co.*, 169 F. Supp. 2d 1119, 1127 (N.D. Cal. 2000), *aff'd*, 361 F.3d 566 (9th Cir. 2004). Moreover, the UCL does not reach claims brought by non-residents concerning conduct that occurred outside of California. *See Norwest Mortg., Inc. v. Super. Ct.*, 85 Cal. Rptr. 2d 18, 24-25 (Cal. Ct. App. 1999) (rejecting a nationwide class seeking recovery under the UCL for injuries suffered by non-California residents caused by conduct outside of California); *J.P. Morgan & Co. v. Super. Ct.*, 6 Cal. Rptr. 3d 214, 221-22 (Cal. Ct. App. 2003) (similar); *see also Ice Cream Distribs. of Evansville, LLC v. Dreyer's Grand Ice Cream, Inc.*, 2010 WL 3619884, at *8 (N.D. Cal. Sept. 10, 2010) (The UCL "does not apply to actions occurring outside of California that injure non-residents"), *aff'd*, 487 F. App'x 362 (9th Cir. 2012). While Plaintiffs have alleged in-state sales, *see* Compl. ¶ 26, they have alleged little else specific to California. Plaintiffs' UCL claim should accordingly be dismissed.

Delaware: The DCFA requires that the challenged conduct "occur in part or wholly within" the state. *Dealer Mgmt. Sys.*, 362 F. Supp. 3d at 548 (dismissing DCFA claim for failure to sufficiently allege that the relevant conduct occurred in Delaware) (quotation marks omitted); *Langdon v. Google, Inc.*, 474 F. Supp. 2d 622, 633 (D. Del. 2007) (same); *Wal-Mart Stores, Inc. v. AIG Life Ins. Co.*, 901 A.2d 106, 117 (Del. 2006) (affirming dismissal for same reason); *see also In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 182 n.33 (D.

Me. 2004) (noting that the “offending conduct itself (not merely the trade or commerce) must occur in Delaware”). Plaintiffs have not alleged any conduct that occurred in Delaware, but merely allege that some unspecified amount of prescriptions were dispensed there. *See* Compl. ¶¶ 26, 368-78. That is insufficient.

Florida: The FDUTPA protects only in-state consumers. *Coastal Physician Servs. of Broward Cnty., Inc. v. Ortiz*, 764 So. 2d 7, 8 (Fla. Dist. Ct. App. 1999). Attenuated contacts with Florida are insufficient to support a claim. *Montgomery v. New Piper Aircraft, Inc.*, 209 F.R.D. 221, 227 (S.D. Fla. 2002). Plaintiffs have not identified in-state consumers injured by the conduct at issue or alleged that any unlawful conduct occurred in Florida. They have thus failed to allege a sufficient nexus to Florida, and their FDUTPA claims should be dismissed. *Hytera Commc’ns Corp. v. Motorola Sols., Inc.*, 2022 WL 3645908, at *21 (N.D. Ill. Aug. 24, 2022) (dismissing FDUTPA claims by non-residents and rejecting argument of nationwide impact); *Goodwin v. Am. Equip. Leasing, LLC*, 2012 WL 13102266, at *3 (M.D. Fla. Aug. 29, 2012) (similar); *Cast Iron*, 2015 WL 5166014, at *34 (similar).

Massachusetts: MCPA § 11 provides a claim only for conduct that “occurred primarily and substantially within” Massachusetts, which focuses on where the “center of gravity of the circumstances that give rise to the claim” occurred. *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639, 681 (D. Mass. 2020) (quotation marks omitted). “[A] place of injury within Massachusetts is not a sufficient basis for finding that conduct occurred primarily and substantially within the Commonwealth.” *Id.* at 682 (quotation marks omitted); *accord New England Gen-Connect, LLC v. US Carburetion, Inc.*, 2019 WL 1332891, at *2 (D. Mass. Mar. 25, 2019). Further, “[w]here wrongdoing is not focused on Massachusetts but has relevant and substantial impact across the country, the ‘primarily’ requirement of section 11 cannot be satisfied.” *Fishman Transducers*,

Inc. v. Paul, 684 F.3d 187, 197 (1st Cir. 2012). Here, no party is a Massachusetts resident, and the Complaint alleges a nationwide scheme not focused on Massachusetts. Compl. ¶¶ 230-33. Therefore, Plaintiffs’ § 11 claim must be dismissed for failure to satisfy the intrastate nexus requirement. *In re Pork Antitrust Litig.*, 495 F. Supp. 3d 753, 788 (D. Minn. 2020) (dismissing § 11 claim where none of the defendants were Massachusetts residents and allegations were of a nationwide conspiracy).

New Hampshire: Courts routinely hold that the NHCPA “requires the proscribed conduct to occur within the state” and that “merely selling a good in New Hampshire is not enough when the proscribed conduct occurs elsewhere.” *In re Lithium Ion Batteries Antitrust Litig.*, 2014 WL 4955377, at *22 (N.D. Cal. Oct. 2, 2014); *see also Miami Prods.*, 546 F. Supp. at 240 (fact that indirect purchasers may have made in-state purchases at “allegedly inflated prices simply does not bring the claimed conduct within the ambit of the NHCPA” absent misrepresentations in the state); *In re Hard Disk Drive Suspension Assemblies Antitrust Litig.*, 2021 WL 4306018, at *16-17 (N.D. Cal. Sept. 22, 2021) (dismissing NHCPA claim for failure to allege that the defendant engaged in conduct within the state). Plaintiffs’ NHCPA claim must be dismissed because the Complaint merely alleges that Copaxone was sold in New Hampshire, not that Teva engaged in any conduct there. Compl. ¶¶ 26, 310-21.

New York: “Numerous courts have held that the deceptive conduct giving rise to the section 349 claim must have occurred in New York state.” *Sheet Metal Workers Loc. 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205, 214 (E.D. Pa. 2009) (collecting cases); *see also Goshen v. Mut. Life Ins. Co. of N.Y.*, 774 N.E.2d 1190, 1195 n.1 (N.Y. 2002) (standard for recovery for § 350 is identical to § 349). An indirect effect on consumers is insufficient. *See Auto. Refinishing*, 515 F. Supp. 2d at 552. The Complaint does not identify the

location of any false or deceptive conduct or misstatements, much less that such alleged acts occurred in New York. Plaintiffs' §§ 349 and 350 claims should be dismissed.

IV. The Complaint Fails To Plausibly Allege Unjust Enrichment Claims.

Plaintiffs assert a count for unjust enrichment under the laws of "all U.S. states and territories." Compl. ¶ 380. In doing so, they make no effort to account for the specific elements of each jurisdiction's laws, thus imposing on Teva and this Court the burden of "sort[ing] out whether or how those laws can act as surrogates for antitrust law." *Aggrenox*, 94 F. Supp. 3d at 255-56. That is improper, as is Plaintiffs' attempt to use unjust enrichment as a catchall claim to end-run the numerous flaws in their other state claims. This count should be dismissed.

A. Plaintiffs' Undifferentiated Unjust Enrichment Claims Fail To Provide Fair Notice Under Each Jurisdiction's Particular Law.

Plaintiffs' unjust enrichment count consists of a scant eight paragraphs purporting to assert claims under the laws of *every single* U.S. state and territory. Compl. ¶¶ 379-86. But rather than plead the elements of unjust enrichment on a jurisdiction-specific basis, Plaintiffs merely allude to the same alleged conduct underlying their other state claims, and then recite generic principles of unjust enrichment in a conclusory fashion. This "formulaic recitation" is insufficient, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), as such "undifferentiated unjust enrichment claims" "provide neither Defendants nor the Court with sufficient information to assess their adequacy," *Miami Prods.*, 546 F. Supp. 3d at 248; *see also Aggrenox*, 94 F. Supp. 3d at 255 (dismissing unjust enrichment claims where pleadings failed "to account for any consequential differences that may exist among the undifferentiated state-law claims").

"[C]obbling together the elements of a claim of unjust enrichment from the laws of the fifty states is no different from applying federal common law," which does not exist. *Wellbutrin XL*, 260 F.R.D. at 167 (dismissing unjust enrichment claims). Indeed, several states, such as

California and Illinois, do not recognize a cause of action for unjust enrichment *at all*. *See, e.g., Refrigerant Compressors*, 2013 WL 1431756, at *25 (California); *Martis v. Grinnell Mut. Reinsurance Co.*, 905 N.E.2d 920, 928 (Ill. App. Ct. 2009) (Illinois). Even where the claim is recognized, “state law requirements under unjust enrichment vary widely.” *Miami Prods.*, 546 F. Supp. 3d at 247-48 (alterations omitted); *Packaged Ice*, 779 F. Supp. 2d at 667 (dismissing undifferentiated unjust enrichment claims). Examples are not hard to find:

- Several states, including Idaho, Kansas, and South Carolina, require a legal relationship, the existence of a duty, or other special circumstances between plaintiff and defendant.³³
- Several states require that the plaintiff confer a direct benefit on the defendant.³⁴
- New York precludes a claim if the relationship with the defendant is “too attenuated.” *Miami Prods.*, 546 F. Supp. 3d at 248.
- Tennessee requires exhaustion of remedies. *Freeman Indus.*, 172 S.W.3d at 525.

Plaintiffs have not pleaded any of these jurisdiction-specific elements. This Court should not fill in the gaps: Plaintiffs’ claim should be dismissed as inadequate under Rule 8. *See Miami Prods.*, 546 F. Supp. 3d at 247-48 (declining to reach specific grounds for dismissal because “Plaintiffs’ conclusory allegations of unjust enrichment do not comply with the relevant pleading standards); *Opana*, 162 F. Supp. 3d at 726 (similar); *Aggrenox*, 94 F. Supp. 3d at 255 (similar).

B. Unjust Enrichment Cannot Be Used To End Run Flaws In Plaintiffs’ Statutory Claims.

Unjust enrichment claims are not a backstop to failed antitrust claims. *See, e.g.,*

³³ *See, e.g., Hayden Lake Fire Prot. Dist. v. Alcorn*, 111 P.3d 73, 91 (Idaho 2005), *overruled on other grounds by Farber v. Idaho State Ins. Fund*, 272 P.3d 467, 473 (Idaho 2012); *Haz-Mat Response, Inc. v. Certified Waste Servs. Ltd.*, 910 P.2d 839, 847 (Kan. 1996); *In re Static Random Access Memory (SRAM) Antitrust Litig.*, 2010 WL 5094289, at *6 (N.D. Cal. Dec. 8, 2010); *In re Microsoft Corp. Antitrust Litig.*, 401 F. Supp. 2d 461, 464 (D. Md. 2005); *Pitts v. Jackson Nat’l Life Ins. Co.*, 574 S.E.2d 502, 511-12 (S.C. Ct. App. 2002).

³⁴ *E.g., In re Novartis & Par Antitrust Litig.*, 2019 WL 3841711, at *7 (S.D.N.Y. Aug. 15, 2019) (dismissing claims based on the laws of eleven states that require a direct benefit); *Refrigerant Compressors*, 2013 WL 1431756, at *25 (same).

Coresello v. Verizon N.Y., Inc., 987 N.E.2d 1177, 1185 (N.Y. 2012) (“[U]njust enrichment is not a catchall cause of action to be used when others fail.”). Plaintiffs “may not employ unjust enrichment to skirt the limitation on recovery imposed by *Illinois Brick*” in jurisdictions that disallow indirect-purchaser suits. *Digital Music*, 812 F. Supp. at 412-13. The same concerns that motivate restrictions on indirect-purchaser antitrust claims—*e.g.*, the possibility of duplicative liability and inefficient enforcement—fully apply when the same claims are repackaged under a new label. *See Terazosin Hydrochloride*, 160 F. Supp. 2d at 1380. Thus, for jurisdictions that follow *Illinois Brick*,³⁵ dismissal of Plaintiffs’ unjust enrichment claims is required because allowing such claims to go forward “would circumvent the policy choice” of the jurisdiction. *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 542 (E.D. Pa. 2010).³⁶

In the remaining jurisdictions, unjust enrichment is still an inappropriate remedy because Plaintiffs can proceed under state antitrust and consumer-protection laws. “Unjust enrichment is an equitable claim that is unavailable where an adequate remedy at law exists.” *Fed. Treasury Enter. Sojuzplodoimport v. Spirits Int’l N.V.*, 400 F. App’x 611, 613 (2d Cir. 2010).³⁷ Plaintiffs

³⁵ At least 21 jurisdictions apply the *Illinois Brick* rule: AK, AR, CO, DE, GA, ID, IL, KY, LA, MA, MO, MT, NJ, OK, PA, PR, SC, TX, VA, WA, WY. *See, e.g., Novartis*, 2019 WL 3841711, at *6 (dismissing unjust enrichment claims under *Illinois Brick*).

³⁶ *See also Sheet Metal*, 737 F. Supp. 2d at 425 (joining courts in dismissing “unjust enrichment claims in those states that explicitly disallow indirect purchasers from pursuing antitrust or consumer protection claims.”); *NMV*, 350 F. Supp. 2d at 211 (“[I]t would subvert the statutory scheme to allow these same indirect purchasers to secure, for the statutory violation, restitutionary relief at common law (or in equity).”).

³⁷ *See also In re Namenda Indirect Purchaser Antitrust Litig.*, 2021 WL 2403727, at *38 (S.D.N.Y. June 11, 2021) (dismissing New York claim because an adequate remedy existed under state antitrust statute); *In re Gen. Motors LLC Ignition Switch Litig.*, 257 F. Supp. 3d 372, 419 (S.D.N.Y. 2017) (dismissing Massachusetts claim because adequate remedy existed at law), *modified on reconsideration*, 2017 WL 3443623 (S.D.N.Y. Aug. 9, 2017); *Thompson v. Bayer Corp.*, 2009 WL 362982, at *6 (E.D. Ark. Feb. 12, 2009) (“In addition, some states do not allow an unjust enrichment claim to survive if there is an adequate remedy at law” and citing cases from 16 states); *Trustmark Ins. Co. v. Bank One, Arizona, NA*, 48 P.3d 485, 491 (Ariz. Ct. App. 2002) (stating that an absence of a legal remedy is an element of an Arizona unjust

have not pleaded an absence of a legal remedy, which supports dismissal. *See Novartis.*, 2019 WL 3841711, at *7 (dismissing unjust enrichment claims that were duplicative of statutory claims); *Reynolds v. Lifewatch, Inc.*, 136 F. Supp. 3d 503, 524 (S.D.N.Y. 2015) (similar).

V. Plaintiffs Cannot Recover For Alleged Conduct That Occurred Outside The Applicable Federal And State Limitations Periods.

Most of the state laws at issue provide for a limitations period of four years or fewer, and none exceeds six years. *See* Appendix C. Plaintiffs filed their Complaint on August 22, 2022. Yet Plaintiffs’ claims challenge conduct dating to 2006. Compl. ¶ 16. These claims are time-barred unless Plaintiffs can establish an exception to the statute of limitations. They fail to do so.

A. The Continuing Violations Doctrine Is Unavailable For Many Claims.

Plaintiffs cannot rely on the continuing violations doctrine. Compl. ¶¶ 248-50. Under that doctrine, “a new cause of action accrues each time the plaintiff is injured by an act of the defendant.” *Allen v. Dairy Farmers of Am., Inc.*, 2014 WL 2610613, at *24 (D. Vt. June 11, 2014). But issues of tolling and claim accrual are governed by state law, *Conn. Gen. Life Ins. Co. v. BioHealth Lab’ys, Inc.*, 988 F.3d 127, 137 (2d Cir. 2021), and several jurisdictions do not recognize the continuing violations doctrine. Moreover, even where the doctrine does apply, it would provide no basis to recover damages on purchases made outside the limitations period.

1. Plaintiffs’ Claims For States That Have Not Adopted The Continuing Violations Doctrine Must Be Dismissed.

The continuing violations doctrine “has received mixed treatment by state courts deciding state antitrust claims.” *Opana*, 162 F. Supp. 3d at 725. The Maine Supreme Court, for example, explained that it has “never adopted the continuing violations doctrine as a means of tolling the statute of limitations.” *McKinnon v. Honeywell Int’l, Inc.*, 977 A.2d 420, 425 (Me. 2009). Other jurisdictions have “declined to apply the continuing violation doctrine” in cases that involve the enrichment claim), *as corrected* (June 19, 2002).

mere “continuing effects” of previous acts. *Lamictal*, 172 F. Supp. 3d at 743 (declining to apply the continuing violations doctrine to New York consumer protection claim brought by plaintiffs alleging they purchased drug products “at artificially inflated prices”); *see also Feltmeier v. Feltmeier*, 798 N.E.2d 75, 85 (Ill. 2003).

Here, Plaintiffs assert claims in at least 14 jurisdictions that have not adopted the continuing violations doctrine or have indicated that they do not apply that doctrine to mere allegations of continuing harm from conduct outside the limitations period: California, D.C., Florida (for FDTPA claims), Illinois, Kansas, Massachusetts, Michigan, Mississippi, Nebraska, New Hampshire, New York, Tennessee, Vermont, and Wisconsin. *See In re Pre-Filled Propane Tank Antitrust Litig.*, 2019 WL 4796528, at *16 (W.D. Mo. Aug. 21, 2019) (dismissing as untimely claims under the laws of, *inter alia*, D.C., Florida, Kansas, Massachusetts, Mississippi, Nebraska, New Hampshire, New York, Tennessee, Vermont, and Wisconsin, and concluding that the continuing violations doctrine would not be applied to antitrust and/or consumer protection claims in those jurisdictions); *Lamictal*, 172 F. Supp. 3d at 743, 746-47 (finding doctrine inapplicable to claims under California, Michigan, and New York law alleging injury from inflated drug prices); *Opana*, 162 F. Supp. 3d at 725 (declining to apply doctrine to extend the limitations period for Kansas and Mississippi and dismissing claims with prejudice); *Feltmeier*, 798 N.E.2d at 85 (declining to apply the doctrine to Illinois claims). Plaintiffs’ claims in these jurisdictions should accordingly be dismissed with prejudice as untimely.

2. Even Where The Continuing Violations Doctrine Applies, Plaintiffs Cannot Recover For Conduct Outside The Limitations Period.

Even in jurisdictions that apply the continuing violations doctrine, Plaintiffs’ potential recovery is limited to overcharges allegedly incurred during the applicable limitations period in each jurisdiction. For example, in states with four-year limitations periods, Plaintiffs may not

recover for damages incurred before August 2018. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 747 (E.D. Pa. Sept. 5, 2014). Thus, even where the continuing violations doctrine applies, Plaintiffs' recovery is limited as follows:

- August 2016 (6 years): Maine (14 Me. Stat. § 752); Vermont antitrust and consumer-protection claims (12 V.S.A. § 511); Wisconsin (Wis. Stat. § 133.18(2)).
- August 2018 (4 years): Arizona (Ariz. Rev. State. § 44-1410(b)); California antitrust and consumer-protection (Cal. Bus. & Prof. Code §§ 16750.1, 17208); Connecticut (Conn. Gen. Stat. § 35-40); D.C. (D.C. Code § 28-4511(b)); Florida (Fla. Stat. § 95.11(3)(f)); Illinois (740 ILCS 10/7(2)); Iowa (Iowa Code § 553.16(2)); Maryland (Md. Code Com. Law § 11-209(d)(1)); Massachusetts (M.G.L. ch. 260, § 5A); Michigan (Mich. Comp. Laws § 445.781); Minnesota (Minn. Stat. § 325D.64); Nebraska (Neb. Rev. Stat. § 59-1612); Nevada (Nev. Rev. Stat. § 598A.220); New Mexico (N.M. Stat. § 57-1-12(A)); New York antitrust (N.Y. Gen. Bus. Law § 340(5)); North Carolina (N.C. Gen. Stat. § 75-16.2); North Dakota (N.D. Cent. Code § 51-08.1-10); Oregon (Or. Rev. Stat. § 646.800(2)); Puerto Rico (P.R. Laws Ann. tit. 10, § 268); Rhode Island (R.I. Gen. Laws § 6-36-23); South Dakota (S.D. Codified Laws § 37-1-14.4); Utah (Utah Code § 76-10-3117(2)); West Virginia (W.Va. Code § 47-18-11).
- August 2019 (3 years): Delaware (10 Del. C. § 8106); Kansas (Kan. Stat. § 60-512); Mississippi (Miss. Code Ann. § 15-1-49(1)); New Hampshire (N.H. Rev. Stat. §§ 508:4, 358-A:3); New York consumer protection (N.Y. C.P.L.R. § 214(2)); Tennessee (Tenn. Code Ann. § 28-3-105).

B. Plaintiffs Cannot Use Fraudulent Concealment To Recover Damages Outside Applicable Limitations Periods.

Plaintiffs also cannot rely on fraudulent concealment to recover damages for alleged injuries incurred outside the applicable limitations periods. *See* Compl. ¶¶ 239-47. Their allegations are subject to Rule 9(b). *See Armstrong v. McAlpin*, 699 F.2d 79, 90 (2d Cir. 1983).

Fraudulent concealment generally requires “(1) that the defendant concealed from [the plaintiff] the existence of his cause of action, (2) that he remained in ignorance of the cause of action until some point within [the limitations period], and (3) that his continuing ignorance was not attributable to lack of diligence on his part.” *State of N.Y. v. Hendrickson Bros.*, 840 F.2d 1065, 1083 (2d Cir. 1988). The overwhelming majority of states require an affirmative act of

concealment before the doctrine can apply; mere passive nondisclosure is insufficient.³⁸ Thus, a “plaintiff alleging fraudulent concealment must establish that its failure to have notice of its claim was the result of” the defendant’s affirmative conduct. *Conmar Corp. v. Mitsui & Co. (U.S.A.)*, 858 F.2d 499, 505 (9th Cir. 1988). Some states also require that the affirmative act of concealment be “independent of and in addition to the original wrongdoing,” *Langer v. Simpson*, 533 N.W.2d 511, 522 (Iowa 1995), and at least one jurisdiction (Kansas) does not recognize the doctrine at all with respect to claims alleging statutory violations, see *Bonin v. Vannaman*, 929 P.2d 754 (Kan. 1996). As to what must be affirmatively concealed, jurisdictions typically require, at a “minimum,” that the defendant have either affirmatively “concealed a material fact about the alleged wrong” or “a fact that would prompt a plaintiff’s inquiry notice.” *In re Processed Egg Prods. Antitrust Litig.*, 2012 WL 1137100, at *3-4 (E.D. Pa. Apr. 4, 2012).

³⁸ See, e.g., *Yumul v. Smart Balance, Inc.*, 733 F. Supp. 2d 1117, 1132 n.18 (C.D. Cal. 2010) (“California views an affirmative act of concealment, rather than mere nondisclosure, as a prerequisite to invocation of the fraudulent concealment doctrine”); *In re Tyson Foods, Inc.*, 919 A.2d 563, 585 (Del. Ch. 2007) (doctrine requires an “affirmative act of ‘actual artifice’ ... that either prevented the plaintiff from gaining knowledge of material facts or led the plaintiff away from the truth”); *Szymanski v. Bos. Mut. Life Ins. Co.*, 778 N.E.2d 16, 27 (Mass. App. Ct. 2002) (doctrine requires “some affirmative act done with intent to deceive” and “mere silence” is insufficient)); *Minn. Laborers Health & Welfare Fund. v. Granite Re, Inc.*, 844 N.W.2d 509, 514 (Minn. 2014) (“any concealment by positive affirmative act and not mere silence is itself fraudulent so as to prevent the statute from running” (alterations omitted)); *Au v. Au*, 626 P.2d 173, 178 (Haw. 1981) (“The acts relied on [for fraudulent concealment] must be of an affirmative character and fraudulent.”); *Jackson v. Georgopolous*, 552 So. 2d 215, 221 (Fla. Ct. App. 1989) (requiring “an affirmative misrepresentation by defendant” to establish fraudulent concealment); *Dancor Int’l Ltd. v. Friedman, Goldberg & Mintz*, 681 N.E.2d 617, 623-624 (Ill. App. Ct. 1997) (there must be “affirmative acts or representations designed to prevent discovery of the cause of action or to lull or induce a claimant into delaying the filing of his claim”); *Doe v. Roman Cath. Archbishop of Archdiocese of Detroit*, 692 N.W.2d 398, 405 (Mich. Ct. App. 2004) (“The acts relied on must be of an affirmative character and fraudulent.”); *Trustmark Nat’l Bank v. Meador*, 81 So. 3d 1112, 1119 (Miss. 2012) (plaintiffs must show “some affirmative act of conduct was done and prevented discovery of the claim”); *Strassburg v. Citizens State Bank*, 581 N.W.2d 510, 515 (S.D. 1998) (“fraudulent concealment consists of some affirmative act or conduct on the part of the defendant” (quotation marks omitted)); *Pero’s Steak & Spaghetti House v. Lee*, 90 S.W.3d 614, 626 (Tenn. 2002).

Under any standard, Plaintiffs fail to plausibly allege affirmative concealment by Teva. Plaintiffs’ allegations boil down to an objection that Teva did not publicize its alleged conduct—not that Teva engaged in concealment, active or otherwise. Plaintiffs allege, for example, that Teva “actively concealed its illegal payments to Medicare recipients by funneling them through” charitable foundations, and kept contracts with PBMs and specialty pharmacies confidential. Compl. ¶¶ 241, 244. But the mere fact that Teva did not disclose *internal* budgeting figures, documents, or communications revealing its donations or contracting strategy (*id.* ¶¶ 128, 241, 244) does not constitute an *affirmative* act of concealment. *See Premium Props. Unlimited, LLC v. Mercantile Bank Mortg. Co., LLC*, 732 F. App’x 414, 418 (6th Cir. 2018) (“[N]ondisclosure [of internal emails] does not constitute an affirmative act of concealment”); *Trustmark*, 81 So. 3d at 1119 (plaintiff “cannot satisfy the ‘affirmative act’ requirement with mere allegations that the other party had complete control of the information” (citation omitted)). Limiting distribution of information to internal stakeholders is hardly an uncommon or suspicious business practice. Moreover, the PBMs who third-party payors like Plaintiffs engaged to negotiate on their behalf were obviously aware of their own negotiations and ultimate contracts with Teva.³⁹

The Complaint falls back on allegations that Teva’s scheme was inherently “self-concealing” because disclosure would have exposed Teva to liability. *E.g.*, Compl. ¶ 240. That charge ignores that many aspects of Teva’s purported “scheme” were public facing, such as its launch of Copaxone 40 mg and its DAW messaging. *See id.* ¶¶ 166-72, 197-99. Moreover, it “would eviscerate the very concept of a limitations period,” *Schmidt v. Skolas*, 770 F.3d 241, 255 (3d Cir. 2014), if that period could be tolled any time a plaintiff alleges that the defendants knew

³⁹ The Complaint’s allegation that Teva “concealed” its copay coupon program for patients on private insurance, Compl. ¶ 242, is contradicted by other allegations that Teva’s copay coupon program was publicly known, *id.* ¶¶ 111-13.

that disclosure of (supposedly unlawful) conduct could expose them to legal consequences.

Even if the Complaint had sufficiently alleged an affirmative act of concealment, its allegations still fall short. First, the Complaint does not allege that Plaintiffs “relied on” any “act of concealment,” *In re Magnesium Oxide*, 2011 WL 5008090, at *23, which requires, at a minimum, that alleged fraudulent acts “were directed toward [Plaintiffs] and that [Plaintiffs] were aware” of them, *In re Magnesium Oxide Antitrust Litig.*, 2012 WL 1150123, at *7-8 (D.N.J. Apr. 5, 2012). Plaintiffs do not try to show that they were aware of any alleged misstatements or acts of concealment, or that they relied on them in deciding not to bring suit sooner. *See In re Magnesium Oxide*, 2011 WL 5008090, at *23 (dismissing fraudulent-concealment claim lacking “allegations that they were misled by Defendants’ concealment of the alleged conspiracy”).

Second, the Complaint alleges that generic uptake in this market was substantially slower than typical, Compl. ¶¶ 82-83, which, if true, should have placed Plaintiffs on inquiry notice of their claims. But Plaintiffs do not plausibly allege that they exercised due diligence in investigating their claims—a basic requirement of fraudulent concealment under both federal and state law⁴⁰ that Plaintiffs have the burden to plead.⁴¹ *See In re Processed Egg Prods. Antitrust*

⁴⁰ *See, e.g., Hendrickson Bros.*, 840 F.2d at 1083; *World Wrestling Ent., Inc. v. THQ, Inc.*, 2008 WL 4307568, at *12 (Conn. Super. Ct. Aug. 29, 2008); *Weisberg v. Williams, Connolly & Califano*, 390 A.2d 992, 996 (D.C. 1978); *Nardone v. Reynolds*, 333 So. 2d 25, 37 (Fla. 1976); *Christy v. Miulli*, 692 N.W.2d 694, 702 (Iowa 2005); *Prospect Cap. Corp. v. Fid. & Deposit Co. of Md.*, 2018 WL 3302168, at *2 (Md. Ct. Spec. App. July 5, 2018); *Taylor v. Philip Morris Inc.*, 2001 WL 1710710, at *6 (Me. Super. Ct. May 29, 2001); *Wild v. Rarig*, 234 N.W.2d 775, 795 (Minn. 1975); *Trustmark*, 81 So. 3d at 1119 (Mississippi); *Chafin v. Wis. Province of Soc’y of Jesus*, 917 N.W.2d 821, 824-25 (Neb. 2018); *Beane v. Dana S. Beane & Co., P.C.*, 7 A.3d 1284, 1290 (N.H. 2010); *Estate of Brice v. Toyota Motor Corp.*, 373 P.3d 977, 981 (N.M. 2016); *Strassburg*, 581 N.W.2d at 515 (South Dakota); *Colosimo v. Roman Cath. Bishop of Salt Lake City*, 156 P.3d 806, 816 (Utah 2007).

⁴¹ *See, e.g., Wild*, 234 N.W.2d at 795; *Christy*, 692 N.W.2d at 702; *Chafin*, 917 N.W.2d at 824; *Estate of Brice*, 373 P.3d at 981; *Com. Bank v. Smith Shellnut Wilson LLC*, 270 So. 3d 136, 154 (Miss. Ct. App. 2018); *see also In re Processed Egg Prods. Antitrust Litig.*, 2011 WL 5980001, at *14 (E.D. Pa. Nov. 30, 2011) (collecting decisions “recogniz[ing] in antitrust suits that

Litig., 2013 WL 4504768, at *5 (E.D. Pa. Aug. 23, 2013) (dismissing claims as time barred for failure to allege diligence where plaintiffs were aware of price increases); *In re Wholesale Grocery Prods. Antitrust Litig.*, 722 F. Supp. 2d 1079, 1086 (D. Minn. 2010) (holding that fraudulent concealment did not toll the statute of limitations due to a lack of diligence where the plaintiffs failed to allege actions taken in response to increased prices).

Here, Plaintiffs allege that they “monitored drug prices for significant increases” and “monitored highly priced brand drugs that had significant member utilization, including Copaxone,” but “lacked the ability to discover” Teva’s allegedly unlawful conduct. Compl. ¶ 246. But although the Complaint alleges that Copaxone’s price increased significantly, *id.* ¶ 59, it never identifies any investigation by Plaintiffs. While Plaintiffs suggest that “[d]rug prices can increase for a variety of reasons,” *id.* ¶ 247, Plaintiffs had “enough information to warrant an investigation” into their claims, *Hexcel Corp. v. Ineos Polymers, Inc.*, 681 F.3d 1055, 1060 (9th Cir. 2012). “Full knowledge often awaits discovery, and the very notion of ‘inquiry notice’ implies something less than that.” *GO Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170, 178 (4th Cir. 2007); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 224 (E.D.N.Y. 2003) (holding that “disclosed facts in the public domain would have been more than adequate to raise [the plaintiffs’] suspicions as to their claim of injury”).

Moreover, Plaintiffs concede that they were on inquiry notice of their claims no later than August and September of 2020, when the DOJ filed a lawsuit against Teva regarding its alleged payments to third-party foundations and a committee of the U.S. House of Representatives issued an investigative report. Compl. ¶ 235. Yet Plaintiffs waited an additional *two years* to file suit—even delaying more than a year after Mylan filed its lawsuit that is based on largely

alleging a plaintiff’s diligence is a required element for pleading fraudulent concealment”).

identical allegations. That is not reasonable diligence. *See Smith v. Davis*, 953 F.3d 582, 598 n.7 (9th Cir. 2020) (en banc) (explaining that “tolling is available only when the plaintiff exercises ‘all due diligence,’ including the diligence required to ‘bring suit within a reasonable time’”).

C. The Discovery Rule Does Not Assist Plaintiffs.

The discovery rule also cannot save Plaintiffs’ claims from being time barred. Under federal law, antitrust claims accrue “when a defendant commits an act that injures a plaintiff’s business”—not when the plaintiff discovers that injury. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 188 (1997). Most states apply the same injury rule to claims arising under state antitrust or consumer protection laws, including, as relevant here: Arizona, California, Connecticut, D.C., Florida, Illinois, Iowa, Kansas, Maine, Michigan, Minnesota, New York, Rhode Island, South Dakota, and Tennessee. *See Hightower v. Celestron Acquisition, LLC*, 2021 WL 2224148, at *9 (N.D. Cal. June 2, 2021); *see also In re Packaged Seafood Prods. Antitrust Litig.*, 242 F. Supp. 3d 1033, 1100 (S.D. Cal. 2017) (injury rule applies to claims in Arizona, California, D.C., Florida, Illinois, Iowa, Kansas, Maine, Michigan, Minnesota, New York, and South Dakota). Plaintiffs cannot rely on the discovery rule for those state-law claims.

Even in jurisdictions that apply the discovery rule for these types of claims, that rule still does not assist Plaintiffs. The discovery rule “requires a plaintiff to inquire into the existence of a cause of action when the plaintiff has access to information that would prompt a reasonable party to do so.” *Hightower*, 2021 WL 2224148, at *9; *see also In re Interior Molded Doors Antitrust Litig.*, 2019 WL 4478734, at *23 (E.D. Va. Sept. 18, 2019). As explained, Plaintiffs should have known about their alleged injury and its cause well before they filed suit, yet they do not allege any steps to investigate their potential claims. *See pp. 68-69, supra*.

CONCLUSION

Teva respectfully requests that the Court dismiss the Complaint in full with prejudice.

Respectfully submitted,

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